

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
BNT162b2 (30 µg)	12-15	C4591001 1007 10071409	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	16-55	C4591001 1001 10011125	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1003 10031143	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051369	C4591001 1005 10051369	Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
C4591001 1005 10051371	C4591001 1005 10051371	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).	
		Dose 2 all-available efficacy	Did not receive 2 vaccinations.	
		Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).	

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			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051378	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051381	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051385	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051393	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1005 10051396	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051400	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051408	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1006 10061180	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071431	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1007 10071434	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071438	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071439	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071440	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071445	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1007 10071447	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071450	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071451	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071452	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071454	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1008 10081492	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081529	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081629	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081688	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081693	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081695	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

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			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081703	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081704	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081710	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081715	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081717	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

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			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081719	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081722	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081727	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081731	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081736	Dose 2 all-available efficacy	Did not receive 2 vaccinations.



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			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081737	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081741	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081743	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081745	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091210	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

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			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091230	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091244	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091254	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091256	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091258	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

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			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091260	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111039	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111232	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111235	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111236	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111237	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1012 10121001	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1012 10121103	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1012 10121163	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131138	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

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			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131544	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131670†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131809	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1015 10151199	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1015 10151259	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1015 10151261	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1015 10151262	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1015 10151265	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1015 10151266	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161047	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161087	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161341	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161345	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161347	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161349	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181028	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181054	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181142	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181165	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181186	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181266	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181310	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181311	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181353	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191166	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191254	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191318	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191321	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1024 10241002	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241004	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241006	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241009	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241014	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241015	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241021	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241023	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241032	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241033	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1024 10241039	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241040	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241042	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241044	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241046	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241054	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241055	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241061	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241066	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241067	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241071	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241072	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241074	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241078	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241084	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1024 10241085	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241091	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241094	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241100	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241102	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241104	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241108	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1028 10281072	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281267	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281282	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281286	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281287	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281291	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1036 10361011	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1036 10361050	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1036 10361127	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1036 10361135	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1036 10361144	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1036 10361145	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371068	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371078	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371337	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1037 10371349	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1038 10381061	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1039 10391224	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391226	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391233	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391234†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391240	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391241	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1042 10421069	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1042 10421251	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1044 10441001	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441015	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441028	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441029	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441031	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441034	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441037	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441045	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1044 10441048	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441050	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441052	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441054	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441060	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441063	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441068	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441071	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441076	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441079	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441088	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441089	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1046 10461285	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461319	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461324	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461327	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461329	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461331	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461333	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461337	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461338	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521064	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521080	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521139	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521143	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541022	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1054 10541055	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541064	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541138	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541204†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541206	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541207	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561013	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1056 10561027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561097	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561146	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561193	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561195	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561271	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561293	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561300	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561316	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561317	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561352	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561361	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561402	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561452	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561516	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561550	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561569	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561576	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561579	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561587	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561588	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561590	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561593	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561594	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561599	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561600	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561606	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561608	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561612	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561613	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561614	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561618	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561622	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561626	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561633	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561634	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561635	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561639	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561643	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571129	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571212	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571279	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571331	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571357	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661198	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661203	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661321	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661332	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661335	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661358	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661386	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661388	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661391	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1068 10681002	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681006	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1068 10681011	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681016	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681021	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681024	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681027	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681034	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681035	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681042	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681046	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681053	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681058	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681060	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681061	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681072	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681073	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1068 10681077	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681081	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1071 10711008	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711095	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711235	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711244	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1071 10711250	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1073 10731038	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791004	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791058	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791079	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791135	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1079 10791252	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791315	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1081 10811071	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1081 10811105	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821078	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1082 10821211	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821215	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821216	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821218	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821220	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1083 10831141	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1083 10831152	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1083 10831197	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841118	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841272	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1084 10841533	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841537	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841538	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1085 10851245	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1085 10851332	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1085 10851373	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871209	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871336	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871557	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1087 10871562	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871582	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871586	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871594	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871595	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871596	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871597	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1088 10881045	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1088 10881077	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1089 10891158	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1089 10891182	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1089 10891311	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1089 10891346	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1089 10891351	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901136	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901510	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1090 10901547	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901548	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901557	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901558	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901559	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1091 10911005	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1091 10911008	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1091 10911015	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1091 10911039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911077	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911130	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911232	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911358	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911380	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911382	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911384	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911386	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1091 10911387	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921128	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921249	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921271	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921272	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931055	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931058	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1093 10931065	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931209	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931211	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931214	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931218	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931219	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931223	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931224	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941186	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941188	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941192	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951110	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951124	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951141	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951168	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951173	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951208	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1095 10951307	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961141	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961287	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961288	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961344	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1098 10981029	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1098 10981169†	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1098 10981189	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1098 10981200	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1101 11011021	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1107 11071018	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1107 11071162	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1109 11091059	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091234	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091349	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091391	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091406	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1109 11091414	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091417	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091422	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091522	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101006	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101069	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101154	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101333	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101374	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101379	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1111 11111064	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1111 11111099	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1111 11111105	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121058	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1112 11121101	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121192	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121229	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121270†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1112 11121331	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1114 11141037	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1116 11161015	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1116 11161143	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1116 11161172	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1116 11161226	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1);



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
				had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1117 11171070	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201299	Dose 1 all-available efficacy	Did not provide informed consent.
			Dose 2 all-available efficacy	Did not provide informed consent.
			Evaluable efficacy (7 days)	Did not provide informed consent; had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not provide informed consent; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1120 11201320	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201363	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1120 11201388	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201398	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201404	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201407	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201409	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1120 11201417	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201418	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201430	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201431	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1121 11211025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1122 11221026	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231027	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231144	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231154	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231168	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231208	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231263	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231301	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231386	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1123 11231403	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231405	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231408	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231410	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231411	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1124 11241049	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1124 11241100	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1125 11251148	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1125 11251159	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1126 11261053	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1126 11261200	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1126 11261202	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1126 11261205	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1127 11271022	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1128 11281126	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291061	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291238	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291249	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1130 11301084	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1130 11301091	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1130 11301093	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1130 11301097	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1131 11311024	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1131 11311257	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1131 11311260	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331052	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331122	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331295	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331316	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331341	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331346	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331509	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331542	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331545	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331546	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331548	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331550	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331551	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331554	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331556	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331557	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331560	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331563	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331564	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331565	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331567	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331570	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331573	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331574	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331575	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331578	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331580	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331582†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331585	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331587	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331589	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331592	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331594	Dose 2 all-available efficacy	Did not receive 2 vaccinations.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331595	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331596	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331601	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331602	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331606	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331609	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331610	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331613	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331614	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331618†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331621	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331622	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331625	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331626	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331629	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331630	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331633	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331636	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331638	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331639	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331640	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331642	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331645	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331648	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341153	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341174	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341177	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341228	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341438	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1135 11351061	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351199	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351389	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351428	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351430	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351480	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351523	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351529	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351536	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351537	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1135 11351539	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351540	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351541	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351545	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351546	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1135 11351548	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351550	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351553	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351554	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351556	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1135 11351559	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351560	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351562	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351565	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351568	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1135 11351569	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351571	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351572	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361043	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361082	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1136 11361086	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361091	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361092	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361098	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361099	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1136 11361108	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361111	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1139 11391130	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1140 11401301	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411011	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1141 11411014	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1141 11411023	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1141 11411065	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1141 11411096	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411127	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411164	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411166	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411179	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411249	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411269	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421293	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421300	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421307	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1142 11421308	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421310	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1145 11451115	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461010	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461340	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461341	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461344	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461346	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461348	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461351	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461354	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461355	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461356	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461359	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461361	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461363	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461367	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461368	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461369	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461371	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461372	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461374	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461378	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461380	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461381	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461382	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461386	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461388	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461390	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461393	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461395	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461398	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1147 11471212	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1147 11471255	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491005	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491067	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491088	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491209	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491334†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491335†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491341	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1150 11501139	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1150 11501140	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1150 11501144	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1150 11501146	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1150 11501147	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1150 11501150	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521034	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521477	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521568	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1152 11521575	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521577	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561006	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561272	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561274	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1156 11561277	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561283	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561286	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561288	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561291	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1156 11561293	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561294	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561295	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561296	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1157 11571070	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1157 11571169	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1161 11611001	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611002	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611006	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611009	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611011	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611014	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
				other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611017	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1161 11611026	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611032	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611034	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611041	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1);

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
				had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1162 11621005	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621118	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621374	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621381	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621391	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621477	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621524	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621549	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621566	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1162 11621583	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621585	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621587	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1163 11631006	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631069	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1163 11631117	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631121	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631124	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631127	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631136	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631142	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631145	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1166 11661097	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1166 11661099	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1166 11661106	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1166 11661109	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1166 11661112	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1167 11671111	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1168 11681030	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701023	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701112	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701205	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701300	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701316	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701344†	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1170 11701404	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701422†	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701432	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701435	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1170 11701441	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701450	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701451	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701452	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701456†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701457†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1);

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
				had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1170 11701459	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701460	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701463†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701466	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701467	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701469	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701471	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701473	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701475	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701476	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701480	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701481	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701483	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701485	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701488	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701490	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701491	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701493	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701496	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701498	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701500	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701501	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711042	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711072	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711151	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1171 11711153	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711214	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711219	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711225	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711229	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711236	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711242	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711249	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1174 11741066†	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1177 11771491	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1177 11771565	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1178 11781061	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1178 11781107	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791137	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791138	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791146	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791148	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791150	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791154	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791158	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791160	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791162	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791167	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791173	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791174	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851002	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851008	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851012	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851013	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851018	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851021	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851022†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851028	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851029	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851036	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851038	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851041	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851049	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851050	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851053	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851054	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851056	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851059	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851066	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851067	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1194 11941061	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1195 11951055	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1195 11951061	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1197 11971042	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971045	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1202 12021010	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1202 12021011	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1203 12031037	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1203 12031063	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1203 12031064	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1204 12041111	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1204 12041267	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1204 12041285	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051012	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1205 12051015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051021	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051024	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1205 12051028	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1205 12051032	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051034	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1205 12051036	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051043	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051044	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051051	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051052	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1205 12051054	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051063	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051064	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051067	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051069	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1205 12051071	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051075	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051077	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051079	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051080	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1207 12071007	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071008	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071011	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071013	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071016	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1207 12071023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071024	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071036	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071037	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1207 12071039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071040	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071041	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071046	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071049	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1207 12071050	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071052	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071058	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071060	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1207 12071062	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071064	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071066	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081004	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081007	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081009	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081012	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081013	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081017	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081018	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081022	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081024	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081026	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081028	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081029	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081034	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081040	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081044	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081045	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081046	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081047	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081050	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081051	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091002	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091006	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091007	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091013	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091016	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091018	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091021	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101009	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101011	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101012	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101017	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101018	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101021	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101024	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101028	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101034	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101036	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101038	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101045	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101046	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101047	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101050	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101051	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101054	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101055	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101060	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101061	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121007	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121009	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121011	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121016	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121017	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121020†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121023	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121024	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121026	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121028	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121034	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121036	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131012	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131013	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131016	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131028	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131036	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131037	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131038	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131041	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131042	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131050	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131052	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131053	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131054	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131059	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141008	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141013	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141016	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141017	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141018	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141029	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141034	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141036	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141037	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141042	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141043	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141045	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141047	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141049	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141052	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141055	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171005†	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1217 12171013	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1217 12171016	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171017	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171021	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171022	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1217 12171030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171034	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171037	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171038	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171040	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1217 12171042	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171045	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171047	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171050	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171052	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1217 12171053	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171056	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171059	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1218 12181007	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1218 12181008	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1218 12181011	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1218 12181014	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1218 12181016	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1218 12181017	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1218 12181019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1219 12191030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1219 12191033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1219 12191034	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201018	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1220 12201026	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201036	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1220 12201042	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201043	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1221 12211025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1221 12211029	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1221 12211030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1221 12211033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1223 12231200	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1223 12231234	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12261072	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1226 12261114	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12261409	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12261797	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262136	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262229	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262255†	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1226 12262262	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262291	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262313	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262356	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1229 12291165†	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1229 12291204	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1230 12301045†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1230 12301099	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1230 12301113	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1230 12301148	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311027	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311125	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311189	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311200	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311409	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311443	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311499	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12311532	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311641	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311801	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311825	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311894	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311911	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311991	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312052	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312077	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312284	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12312339	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312361	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312365	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312372	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312375	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312403	Dose 2 all-available efficacy	Did not receive 2 vaccinations.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312435	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312451	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312559	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312577	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313006	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313175	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313207	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313225	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313289	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313357	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12313428	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313429	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313449	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313456	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313459	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313467	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313469	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313479	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1);

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
				had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1231 12313483	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
			Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1231 12313486	Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313487	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313492	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313497	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313498	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313501	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313505	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12313506	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313508	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313509	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313512	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1);

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
				had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313514	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313515	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313517	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313518	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313519	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313528	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313533	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313534	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1);

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
				had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313537	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313541	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313542	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313546	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313551	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313553	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313554	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12313556	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313564	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313567	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313592	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313622	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12313662	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313709	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313869	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313892	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313967	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314179	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314205	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314290	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314314	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314385	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314416	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12314502	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314525	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314580	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314590	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314700	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314713	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315189	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315204	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315223	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315269	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315308	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315429	Dose 2 all-available efficacy	Did not receive 2 vaccinations.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315441	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315518	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315600	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321037	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321101	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321175	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321219	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321233	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1232 12321250	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321293	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321299	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321305	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321354	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321361	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321396	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321401	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321404	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321408	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321412	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321415	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321416	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321419	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321420	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321423	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321425	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321427	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321428	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321431	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321434	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1235 12351188	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1235 12351230	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1235 12351231	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12411132	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12411144	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12411482	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12411766	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12411993	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12412198	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12412382	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12412403	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12412426	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12412478	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1246 12461025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1247 12471054	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1247 12471149	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1247 12471151	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481025	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481048	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481169	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1248 12481175	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511095	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511259	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511262	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1254 12541005	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541008	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541027	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541029	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541030	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541033	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541035	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541038	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541040	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541142	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1254 12541154	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1258 12581071	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1258 12581072	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1258 12581075	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1260 12601002	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1260 12601005	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1260 12601006	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1260 12601009	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1260 12601013	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1260 12601014	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1260 12601016	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1260 12601017	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1260 12601029	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1260 12601032	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1260 12601036	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1260 12601049	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1260 12601126	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1261 12611054	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1264 12641212	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1264 12641221	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1264 12641226	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1264 12641227	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1264 12641228	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1265 12651164†	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1265 12651186†	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1270 12701148	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1270 12701149	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1270 12701151	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1270 12701153	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441043	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441134	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441135	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441273	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441569	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441572	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441818	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441951	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442058	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442062	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442065	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442070	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442080	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442084	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442085	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442087	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442088	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442093	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442113	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442114	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442131	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442135	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442157	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442159	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442174	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442188	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442190	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442194	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442197	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442199	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442216	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442217	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442219	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442226	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442236	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442241	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442245	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442250	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442255	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442262	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442268	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442269	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442270	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442277	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442278	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442283	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442287	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442288	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442298	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442306	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442313	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442314	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442319	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	>55	C4591001 1003 10031120	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1005 10051214	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051293	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1005 10051372	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051373	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051374	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051382	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051387	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1005 10051389	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051395	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051402	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051403	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051406	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1007 10071105	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1007 10071213	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071430	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081689	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081694	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081699	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081705	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081707	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081709	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081714	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081718	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081724	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081726	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081732	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081734	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081740	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111028	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111181	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111201	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1012 10121139	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1012 10121149	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131176	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1013 10131186	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131714	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131775	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1015 10151258	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161026	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161162	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1019 10191201	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191299	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191307	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191314	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191316	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1019 10191319	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191322	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1021 10211221	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1022 10221150	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1024 10241003	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241010	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241018	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241019	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241031	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241037	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241041	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241049	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241057	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1024 10241059	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241065	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241068	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241077	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241081	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241083	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1024 10241087	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241096	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241097	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1024 10241134†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1027 10271206†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281268	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1028 10281288	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281295	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281296	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1030 10301158	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1036 10361143	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1037 10371057	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371275	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371356	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1039 10391019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1039 10391227	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391230	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391238	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1044 10441002	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441004	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441007	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1044 10441010	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441016	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441018	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441032	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441036	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441041	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441047	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441049	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441055	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441062	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441067	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441073	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441075	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441080	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441083	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1044 10441085	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441090	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441092	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441093	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441094	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1044 10441113	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1044 10441214	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461084	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461245	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461320	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461326	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461328	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1046 10461335	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1047 10471122	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1047 10471228	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1047 10471300	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521062	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521142	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1054 10541071	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541175	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541209†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541210	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541211	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561034	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561078	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561095	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561120	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561123	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561229	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561298	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561301	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561303	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561306	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561353	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561399	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561404	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561409	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561551	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561556	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561598	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1056 10561603	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561605	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561616	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561625	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561630	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1056 10561640	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561641	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571359	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571361†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661128	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1066 10661384	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1068 10681004	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681005	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681008	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681009	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681019	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681023	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1068 10681029	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681030	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681039	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681041	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681044	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681050	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681056	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681057	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681059	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681062	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681068	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681078	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681079	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681084	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1071 10711023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711169	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711178	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711243	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711248	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1072 10721065	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1077 10771271	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791234	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791264	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791271	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791283	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791314	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1080 10801064	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1080 10801217	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1081 10811053	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1081 10811061	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1081 10811139	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1081 10811150	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821062	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821126	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821213	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821223	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1083 10831173	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1084 10841446	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841523	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871080	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871121	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871224	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1087 10871418	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871434	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871512	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871566	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871567	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871585	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871587	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871590	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1088 10881122	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1088 10881139	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1089 10891093	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901237	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901549	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901553	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901555	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901560	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901562	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901568	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911001	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1091 10911004	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1091 10911010	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1091 10911012	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1091 10911092	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911159	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911195	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921015	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921180	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921268	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921273	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921275	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931005	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931190	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931227	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1094 10941046	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941071	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941159	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941184	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941187	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951102	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1097 10971003	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1097 10971024	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1097 10971097	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1097 10971107	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1097 10971121	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1097 10971123	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1098 10981030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1098 10981092	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1098 10981109	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1098 10981162	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1101 11011027	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1101 11011120	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091259	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091345	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091374	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1109 11091475	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091503	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101309	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101373†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101376	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1111 11111205	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121118	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121134	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121255	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1116 11161117	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1116 11161227	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1117 11171047	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1118 11181072	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1118 11181128	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1118 11181130	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201350	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201359	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201368	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201383	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201389	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201403	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201408	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201412	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201414	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201415	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201421	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201422	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201426	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201428	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201435	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1121 11211071	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1);

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
				had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1122 11221034†	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1123 11231406	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1125 11251222	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1125 11251228	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1127 11271002	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1127 11271034	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1128 11281313	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1128 11281325	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291091	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1129 11291117	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
				other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1129 11291149	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291242	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291248	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1130 11301039	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1130 11301095	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1130 11301096	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1131 11311256	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1131 11311259	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1131 11311262	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331197	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331472	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341052	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341099	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341101	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341353	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351131	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361080	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361089	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361096	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361102	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361103	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361107	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1140 11401312	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1140 11401313	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411066	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1141 11411268	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421111	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1142 11421302	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421304	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421311†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421312	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1145 11451113	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491117	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491126	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491224	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491239	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491278	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491296	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521359	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521476	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521497	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521565	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521567	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521572	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521579	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521580	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521581	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521582	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561267	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561284	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561285	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1157 11571144	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1157 11571178	Dose 2 all-available efficacy	Did not receive 2 vaccinations.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1161 11611012	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611013	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611022	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611030	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1);

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
				had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611036	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611037	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1161 11611042	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1162 11621006	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621007	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621212	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621327	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621349	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621407	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621433	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1163 11631005	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631011	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631013	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631126	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631131	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631132	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631133	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631144	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631149	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1166 11661098	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1166 11661102	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1166 11661107	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1167 11671122	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1167 11671123	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1168 11681015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1168 11681235	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1168 11681240	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1169 11691070	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701067	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701160	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701354	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711160	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711217	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711218	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711227	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711233	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711243	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1177 11771232	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791151	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791157	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791163	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791168	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791171	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851001	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851006	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851016	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1185 11851034	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851044	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851046	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851047	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1185 11851058	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851065	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971036	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971037	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971047	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1202 12021001	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1202 12021003	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1202 12021005	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1202 12021012	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1203 12031039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1203 12031068	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1205 12051018	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051037	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051038	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051040	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051045	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1205 12051055	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051058	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051060	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051072	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1207 12071015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071034	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1207 12071056	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071068	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071069	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081014	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081036	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1208 12081041	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091005	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101043	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101044	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1212 12121033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131009	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131021	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131022	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1213 12131027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131049	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131051	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131058	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1214 12141010	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141021	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141028	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141046	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1214 12141050	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171024	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171036	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171043	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1217 12171058	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171060	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1219 12191027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1219 12191036	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201038	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1221 12211021	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1221 12211028	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1223 12231215	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1223 12231250	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1224 12241012	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1229 12291041	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311709	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311815	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312098	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312222	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312496	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313003	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313359	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313391	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313446	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313461	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313468	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313478	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12313480	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313496	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313503	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313511	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313524	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313530	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12313536	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313538	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313549	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313562	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12313651	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314060	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314216	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314301	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314488	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315018	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315246	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1232 12321105	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321144	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321326	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321367	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321403	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321407	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321409	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321411	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321432	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1235 12351227	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12412567†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481026	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481044	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481047	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481182	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1248 12481214	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511050	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1251 12511087	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511236	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511260	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511261	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511267	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1252 12521003	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1254 12541002	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541004	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541010	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541011	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541014	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541016	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541018	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541019	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541025	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541026	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1254 12541037	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1254 12541200	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1260 12601003	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1260 12601008	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1260 12601025	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1260 12601026	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1260 12601027	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1260 12601033	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1260 12601095	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1264 12641222	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1264 12641223	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441495	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441792	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442012	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442076	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442078	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442092	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442098	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442110	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442112	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442130	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442176	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442183	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442187	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442204	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442208	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442239	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
Placebo	12-15	C4591001 4444 44442266	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442271	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442295	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442316	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071415	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091212	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
		C4591001 1009 10091229	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
C4591001 1009 10091229	Dose 2 all-available efficacy	Did not receive 2 vaccinations.		

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161316	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	16-55	C4591001 1003 10031140	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051308	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051341	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051370	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051377	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051380	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051386	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051390	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051394	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051397	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051398	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051407	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1006 10061070	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1006 10061099	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1006 10061176	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1006 10061179	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1006 10061181	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071095	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071276	Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1007 10071407	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071408	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071427	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071433	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071435	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071436	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071441	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071442	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071443	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071444	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071448	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071449	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071455	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081682	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081692	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081696	Dose 2 all-available efficacy	Did not receive 2 vaccinations.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081698	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081700	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081706	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081712	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081713	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081716	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081720	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081721	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081728	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081733	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081738	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081739	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081742	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081744	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081746	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091211	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091253	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091255	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091257	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091259	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091261	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091262	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111070	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111175	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111186	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1011 10111211	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111233	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111234	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131017	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131034	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1013 10131040	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131216	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131426	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131740	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131746	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1015 10151134	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1015 10151257	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1015 10151260	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1015 10151263	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1015 10151267	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1015 10151268	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161126	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161167	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161346	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161348	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181036	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181313	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181340	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1018 10181345	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191098	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191312	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191315	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1024 10241132	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1027 10271105	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281026	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1028 10281241	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1028 10281279	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281280	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281284	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281285	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281290	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1028 10281294	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1036 10361128	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371077	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1038 10381057	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391021	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391080	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391220	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391225	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391232	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391235	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391237	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391239	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391242	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391243	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391244	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1042 10421250	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1042 10421266	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1044 10441188	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461040	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461093	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461099	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1046 10461140	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461318	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461321	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461323	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461325	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461330	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461332	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461334	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461336	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461339	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461340	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1047 10471176	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1047 10471221	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1047 10471314	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521054	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521058	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541150	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541192	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541201	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541208	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541212†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541214	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541215	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1055 10551145	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561098	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561129	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561152	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561192	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561194	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561226	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1056 10561320	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561354	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561372	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561384	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561395	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561396	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1056 10561400	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561403	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561414	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561445	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1056 10561554	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561591	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1056 10561592	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561595	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561596	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561601	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561602	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1056 10561609	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561610	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561611	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561617	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561621	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1056 10561623	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561627	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561629	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561632	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561636	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1056 10561638	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561642	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571031	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571211	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571215	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571248	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571268	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571358	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571362†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661322	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661389	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661390	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1068 10681010	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1071 10711162	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711185	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711211	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711237	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711246	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711247	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711249	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1072 10721051	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1077 10771272	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791082	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791130	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1079 10791143	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791162	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791253	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791267	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821013	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1082 10821077	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821212	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821217	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821221	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821224	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1083 10831029	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1083 10831060	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841503	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841535	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1084 10841536	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841539	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1085 10851286	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1085 10851374	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1085 10851375	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1087 10871089	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871186	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871354	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871356	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871583	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871584	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871588	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871593	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871599	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871601	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1088 10881080	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1089 10891076	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901068	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901245	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901334	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1090 10901379	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901507	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901516	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901546	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901550	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901551	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1090 10901565	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901566	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911014	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1091 10911083	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911291	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911352	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911376	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911378	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911379	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911381	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911383	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911385	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921080	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921158	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1092 10921175	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921274	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921276	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931072	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931094	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931208	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931210	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931215	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931216	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931217	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931222	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931226	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941155	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941189	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951056	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951144	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951197	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1095 10951306	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1096 10961031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1096 10961081	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961276	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961321	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961345	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961388	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961390	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961391	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1097 10971085	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1097 10971120	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1098 10981001	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1098 10981155	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1098 10981168†	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1098 10981219	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1101 11011024	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1101 11011118	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1107 11071160	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1107 11071178	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091068	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091127	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091335	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091478	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091515	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091518	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091526	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091547	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091556	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1110 11101038	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101072	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101085	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101110	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101155	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101156	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101229	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101247	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101250	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101342	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101371	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101372	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101375	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101377	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1111 11111104	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1111 11111139	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1114 11141065	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1116 11161292	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1117 11171138	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1117 11171186	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1117 11171190	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201013	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201038	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201085	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201104	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201249	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201252	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201367	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201392	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201393	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201405	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201406	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201416	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201420	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201425	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201427	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201433	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1122 11221006	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231290	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231313	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231404	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231407	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1123 11231409	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1124 11241003	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1124 11241084	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1125 11251019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1125 11251160	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1125 11251238	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1126 11261074	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1126 11261201	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1126 11261203	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1126 11261204	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1126 11261206	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1126 11261207	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1127 11271099	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1128 11281012	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1128 11281093	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1128 11281146	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1128 11281368	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291048	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291165	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291255	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1130 11301092	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1130 11301094	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1130 11301099	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1131 11311193	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1131 11311263	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331037	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331042	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331059	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331087	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331120	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331138	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331162	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331170	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331207	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331291	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331338	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331510	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331512	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331540	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331541	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331543	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331544	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331547	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331549	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331552	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331553	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331555	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331558	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331559	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331561	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331562	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331566	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331568	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331569	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331571	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331572	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331577	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331579	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331581	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331583	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331584	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331586	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331588	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331590	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331591	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331593	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331598	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331600	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331603	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331604	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331605	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331612	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331615	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331616	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331617	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331619	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331624	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331627	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331628	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331631	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331632	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331634	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331635	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331637	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331641	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331643	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331644	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331646	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1133 11331647	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351132	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351200	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351212	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351420	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351464	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351506	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351517	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351534	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351535	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351538	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351542	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351543	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351544	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351547	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351549	Dose 2 all-available efficacy	Did not receive 2 vaccinations.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351551	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351552	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351555	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351557	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351558	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351561	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351563	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351564	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351566	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351567	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351573	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361045	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361083	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361084	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361087	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361090	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361094	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361095	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361100	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361101	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361109	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1139 11391131	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1140 11401306	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1140 11401311	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1140 11401314	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411146	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411256	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411270	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421299	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421303	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421306	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421313	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1145 11451063	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461288	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461293	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461328	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461339	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461342	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461343	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461345	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1146 11461347	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461349	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461350	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461352	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461353	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1146 11461357	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461358	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461360	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461364	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461365	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1146 11461366	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461370	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461373	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461375	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461376	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1146 11461377	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461379	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461384	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461385	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461387	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1146 11461389	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461391	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461394	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461397	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1146 11461399	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1147 11471035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1147 11471256	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491065	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491066	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491172	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1149 11491230	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491331	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491337†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491339†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491340	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1149 11491343	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491344†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1150 11501138	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1150 11501141	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1150 11501142	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1150 11501145	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1150 11501148	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1150 11501149	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521085	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1152 11521566	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521569	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521570	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521571	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521583	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1152 11521584	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1156 11561033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561200	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561273	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561275	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561276	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561281	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561282	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561287	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561289	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561290	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561292	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561297	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561298	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561299	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1157 11571003	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1157 11571135	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1157 11571156	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1161 11611004	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1);

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
				had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611005	Evaluable efficacy (14 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2. Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611007	Evaluable efficacy (14 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2. Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611008	Evaluable efficacy (14 days) Dose 2 all-available efficacy	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2. Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
				other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611010	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611016	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1);



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
				had other important protocol deviations on or prior to 7 days after Dose 2.
		C4591001 1161 11611018	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611024	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611027	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611028	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1);

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
				had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611040	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1162 11621024	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621217	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621294	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1162 11621310	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621356	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621514	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621515	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621576	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1162 11621584	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621586	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1163 11631039	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631059	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1163 11631096	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1166 11661047	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1166 11661091	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1166 11661103	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1166 11661104	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1166 11661110	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1167 11671003	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1167 11671223	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1168 11681070	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1168 11681104	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1168 11681227	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1168 11681234	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1168 11681241	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1169 11691058	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701015	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701059	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701064	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701117	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1170 11701201	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701308	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701311	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701334†	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1170 11701364	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701427†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1170 11701449	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701453	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701455	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701458	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701461	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701462	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701464	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701465	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701468	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701470	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701472	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701474†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701477	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701478	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701479	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701482	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701484	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701486	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701487	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701489	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701492	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701494	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701495	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701497†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701499	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711101	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711131	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711154	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711159	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711189	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711216	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711221	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1171 11711224	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711226	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711228	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711231	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711241	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711247	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711248	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711250	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711301	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1177 11771139	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1177 11771292	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1177 11771552	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1177 11771564	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1178 11781316	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791143	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791145	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791147	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791149	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1179 11791152	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791153	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791159	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791161	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791165	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1179 11791166	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791170	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851005	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851009	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851010	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1185 11851011	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851017	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851024	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1185 11851030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851032	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851037	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1185 11851040	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851043	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851048	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851051	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851052	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1185 11851055	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851060	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851063	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851064	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971040	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971041	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1202 12021007	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1202 12021009	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1203 12031066	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1203 12031067	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1203 12031069	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1204 12041197†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051011	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051013	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051014	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051017	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051022	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051026	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051029	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051041	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051042	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051047	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051048	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051049	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051050	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051061	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051062	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051065	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051066	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051068	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051073	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051074	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051078	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071006	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071009	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071010	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071012	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071014	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071018	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071021	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071025	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071026	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071028	Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071032	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071038	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071042	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071044	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071045	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071047	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071048	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071051	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071053	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071054	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071059	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071061	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071065	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071067	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081005	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081008	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081010	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081011	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081016	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081021	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081032	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081037	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081038	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081042	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081043	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081048	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081049	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081052	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081053	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081054	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091004	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091008	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091009	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091010	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091011	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091017	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101008	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101010	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101013	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101014	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101016	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101022	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101026	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101029	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101032	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101037	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101040	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101041	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101048	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101049	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101052	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101053	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101056	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101058	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101059	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121008	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121010	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121012	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121013	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121014	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121018	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121022	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121029	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121032	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131010	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131014	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131018	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131026	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131032	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131034	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131040	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131043	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131044	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131046	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131055	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131056	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131060	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141007	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141009	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141012	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141014	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141022	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141024	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141038	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141040	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141041	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141044	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141048	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141051	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141053	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141054	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171014	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171015†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171018	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171028	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171032	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171041	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171044	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171046	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171048	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171049	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171051	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171054	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171055	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171061	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171062	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1218 12181009	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1218 12181012	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1218 12181013	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1218 12181015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1218 12181018	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1219 12191026	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1219 12191028	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1219 12191029	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1219 12191035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201028	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201029	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201032	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201037	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201041	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201044	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1221 12211007	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1221 12211020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1221 12211022	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1221 12211023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1221 12211026	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1221 12211031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1221 12211032	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1223 12231174	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1224 12241009	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1224 12241065	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1224 12241158†	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1226 12261380	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12261391	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12261894	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262063	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262108	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262189	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262267	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262278	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262339	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1230 12301065	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1230 12301150	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311054	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311087	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311088	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12311147	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311191	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311195	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311301	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311356	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311374	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311391	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311402	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12311420	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311431	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311441	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311473	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311516	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12311559	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311568	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311656	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311816	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311858	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311926	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312176	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312244	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312320	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312326	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312334	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312426	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312439	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312483	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312594	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312623	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312660	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312752	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312763	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312848	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312868	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312916	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313068	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313069	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313098	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313115	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313125	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313211	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313376	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313395	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313443	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313454	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313510	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313516	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313527	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12313657	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313758	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313939	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314134	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314266	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314381	Dose 2 all-available efficacy	Did not receive 2 vaccinations.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314492	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314679	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314738	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314848	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314857	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314923	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314984	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315322	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315357	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315681	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321100	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321142	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321213	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1232 12321220	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321244	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321287	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321310	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321377	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321378	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321400	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321402	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321406	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321413	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321414	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321417	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321421	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321422	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321424	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321426	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321429	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321430	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321433	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321435	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1235 12351027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1235 12351071	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1235 12351167	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1235 12351187	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1235 12351224	Dose 2 all-available efficacy	Did not receive 2 vaccinations.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1235 12351225	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1235 12351226	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1235 12351228	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12411260	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12411273	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12411279	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1241 12411688	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12411695	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12412348	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1241 12412355	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12412476	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12412518	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12412534	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12412566†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1248 12481018	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481046	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481060	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481110	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481170	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481199	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481218	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511207	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511254	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1254 12541116	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1254 12541199	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1258 12581070	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1258 12581073	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1258 12581074	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1260 12601070	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1264 12641018	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1264 12641225	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1269 12691081	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1270 12701056	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1270 12701146	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1270 12701147	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1270 12701150	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1270 12701152	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441007	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441044	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441048	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441079	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441179	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441522	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441560	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441912	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441931	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441938	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441979	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442059	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442069	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442071	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442072	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442077	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442081	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442086	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442090	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442091	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442095	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442100	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442101	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442105	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442107	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442115	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442117	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442119	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442140	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442142	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442151	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442156	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442160	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442161	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442162	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442165	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442168	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442170	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442196	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442205	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442212	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442215	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442232	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442233	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442237	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442249	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442253	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442256	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442263	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442274	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442279	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442281	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442284	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442285	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442292	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442293	Dose 2 all-available efficacy	Did not receive 2 vaccinations.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442294	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442297	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442301	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442303	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442304	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442307	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442308	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442310	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442315	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442322	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	>55	C4591001 1005 10051338	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051375	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051379	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051391	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051392	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051399	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1005 10051405	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1006 10061020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1006 10061178	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071114	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1007 10071315	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1007 10071347	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1007 10071432	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081639	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081687	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081690	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081691	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1008 10081697	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081701	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081702	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081708	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081711	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1008 10081723	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081725	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081729	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081730	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1008 10081735	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1009 10091020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091089	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1009 10091157	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111029	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111085	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111086	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1011 10111231	Dose 2 all-available efficacy	Did not receive 2 vaccinations.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131097	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1013 10131192	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161166	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1016 10161282	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191033	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191300	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191309	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191310	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191311	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191313	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191317	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191320	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1019 10191323	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1022 10221015	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1022 10221057	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1024 10241130†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1024 10241133†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281270	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281272	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281283	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281289	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281292	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1028 10281293	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1030 10301157	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1036 10361133	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371117	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371195	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371303	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1037 10371333†	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1038 10381056	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391228	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391229	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1039 10391231	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1042 10421010	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1044 10441116	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1044 10441208	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461126	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461259	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461301	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461309	Dose 2 all-available efficacy	Did not receive 2 vaccinations.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461310	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1046 10461322	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1047 10471252	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1047 10471323	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1052 10521020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541024	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1054 10541186	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541205	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1054 10541213†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1055 10551039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1055 10551248	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561015	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561018	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561032	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561079	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561099	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561232	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561275	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561276	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561302	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561337	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561371	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561381	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561415	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561426	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561589	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1056 10561597	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561604	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561607	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561615	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561619	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1056 10561620	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561628	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1056 10561637	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571128	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1057 10571335†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661350	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661373	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661385	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1066 10661387	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1068 10681043	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1068 10681063	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1071 10711049	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711063	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711216	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1071 10711245	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1072 10721037	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791158	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791266	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1079 10791279	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821007	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821164	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821214	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1082 10821219	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841006	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841366	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1084 10841507	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871033	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1087 10871211	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871228	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871505	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871560	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871589	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1087 10871591	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1087 10871600	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1088 10881260	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1089 10891004	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1089 10891344	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901146	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901415	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901519	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901545	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901552	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901554	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901556	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901563	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901564	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1090 10901569	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1091 10911006	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1092 10921123	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921191	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921267	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921277	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1092 10921278	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931050	Dose 2 all-available efficacy	Did not receive 2 vaccinations.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931051	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931128	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931191	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1093 10931212	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941080	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941130	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941183	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1094 10941191†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1095 10951107	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1096 10961048	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961082	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961086	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961160	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1096 10961282	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1097 10971033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1097 10971047	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1097 10971060	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1097 10971122	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1101 11011077	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1101 11011119	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1107 11071093	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091101	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091248	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091313	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1109 11091407	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101241	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101367	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1110 11101378	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1111 11111106	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121052	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1112 11121337	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1116 11161118	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1116 11161253	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1117 11171040	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1117 11171052	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1118 11181065	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1118 11181129	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201066	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201073	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201127	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201213	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201227	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201335	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1120 11201351	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201353	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201360	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201361	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201382	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1120 11201390	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201397	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201399	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201400	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201410	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1120 11201411	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201413	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201419	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201423	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201424	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1120 11201432	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1120 11201434	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1122 11221058	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1124 11241048	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1125 11251107	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1125 11251211	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1125 11251227	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1125 11251229	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1127 11271003	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1128 11281023	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1128 11281109	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291082	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291237	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291247	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1129 11291254†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1130 11301098	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1131 11311145	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1131 11311164	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1131 11311258	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331426	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331469	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1133 11331481	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341067	Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria.
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria.
		C4591001 1134 11341087	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341130	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341339	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1134 11341439	Dose 2 all-available efficacy	Did not receive 2 vaccinations.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1135 11351128	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361077	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361085	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361088	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361093	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361097	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361104	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361105	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361106	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1136 11361110	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1140 11401035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1140 11401082	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1141 11411196	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421301	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421305	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1142 11421309	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1145 11451076	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1145 11451114	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1147 11471004	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491338	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1149 11491342†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521573	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521574	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521576	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521578	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521585	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1152 11521586	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561044	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561092	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561278	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1156 11561279	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1156 11561280	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1157 11571028	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1157 11571131	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1161 11611003	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1161 11611021	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611025	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611029	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611031	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1161 11611038	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611043	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1161 11611044	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1162 11621213	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1162 11621278	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1162 11621297	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1163 11631003	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631007	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631008	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631010	Evaluable efficacy (7 days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1163 11631100	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1166 11661100	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1166 11661105	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1166 11661108	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1166 11661111	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701448	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1170 11701454†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711215	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711220	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711222	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711230	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711232	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711235	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1171 11711244	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1177 11771089	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1177 11771538	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1178 11781056	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1179 11791141	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791155	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791156	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791164	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1179 11791169	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1179 11791172	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851003	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851004	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851007	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851014	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1185 11851019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851042	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851045	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1185 11851061	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1185 11851062	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1194 11941027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971038	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971046	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1197 11971052	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1202 12021002	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1202 12021004	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1202 12021006	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1202 12021008	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1203 12031061	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1204 12041057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051016	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051019	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1205 12051039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051046	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051053	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051056	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051059	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1205 12051070	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1205 12051076	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071017	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071022	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1207 12071029	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071035	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071043	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071055	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1207 12071063	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1208 12081006	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081015	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1208 12081055	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091012	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1209 12091014	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1210 12101042	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1210 12101062	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1212 12121021†	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131011	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131017	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1213 12131023	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131024	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131029	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131030	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131045	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1213 12131047	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1213 12131048	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141006	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141011	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141026	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1214 12141032	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1214 12141033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171026	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171029	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1217 12171033	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1217 12171057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1218 12181020	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1219 12191025	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1219 12191031	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1219 12191032	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1219 12191037	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201034	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1220 12201040	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1221 12211017	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1221 12211018	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1221 12211027	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1224 12241057	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1224 12241157	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
			Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Randomized but did not meet all eligibility criteria; did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12261613	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1226 12262240	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1229 12291080†	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311057	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12311549	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311672	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1231 12311723	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311935	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12311979	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312130	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312347	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12312571	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313039	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313090	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313103	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12313457	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314120	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314189	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314863	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12314972	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315608	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1231 12315625	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1231 12315672	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321127	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321234	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321242	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321281	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321405	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321410	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1232 12321418	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1235 12351221	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1241 12412568	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1247 12471066	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1247 12471135	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1247 12471166	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1248 12481049	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511047	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511067	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511078	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511258	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511263	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511264	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1251 12511265	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 1258 12581076	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1260 12601030	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1260 12601121	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1264 12641195	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1264 12641220	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1264 12641229	Dose 2 all-available efficacy	Did not receive 2 vaccinations.

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1264 12641230	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 1265 12651026	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 14 days after Dose 2.
		C4591001 1270 12701057	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44441152	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442061	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442074	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442075	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442096	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442108	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442116	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442126	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442127	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442132	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442134	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442139	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442141	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442150	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442164	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442166	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
		C4591001 4444 44442169	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442179	Dose 2 all-available efficacy	Did not receive 2 vaccinations.
			Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442243	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442282	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442290	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442296	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		C4591001 4444 44442309	Evaluable efficacy (7 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
			Evaluable efficacy (14 days)	Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Populations

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Population	Reason for Exclusion
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Note: HIV-positive subjects are included in this listing but not included in the analyses of the overall study objectives.

Note: † = HIV-positive subject.

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(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2\_unblinded/C4591001\_Efficacy\_FA\_164/adsl\_1001\_excl\_eff

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
12-15	C4591001 1005 10051317	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051328	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051339	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071409	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071414	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071415	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071417	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071428	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071429	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091205	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091208	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091209	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091212	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091213	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091216	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1009 10091218	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091220	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091221	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091223	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091226	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091227	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091229	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091231	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091233	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091234	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091237	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091238	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091240	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091246	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091247	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1009 10091249	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091250	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161309	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161314	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161315	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161316	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161318	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161319	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161320	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161322	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161323	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161324	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161325	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161326	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161327	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1016 10161329	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161330	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161331	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161332	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161334	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161335	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161336	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161337	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161338	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161339	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161340	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161343	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161344	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501119	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501120	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1150 11501123	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501124	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501125	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501126	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501127	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501128	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501129	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501130	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501131	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501132	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501133	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501134	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501135	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501136	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561246	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1156 11561247	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561248	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561249	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561250	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561253	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561254	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561255	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561256	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561257	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561259	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561260	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561262	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561263	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561264	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561265	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
16-55	C4591001 1001 10011125	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1003 10031140	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
	C4591001 1003 10031143	Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
	C4591001 1005 10051223	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
	C4591001 1005 10051224	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
	C4591001 1005 10051243	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
	C4591001 1005 10051251	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051254	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051257	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051260	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051268	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051276	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051277	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051280	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1005 10051281	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051283	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051285	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051288	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051290	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051291	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051292	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051294	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051295	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051301	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051302	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051308	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051310	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051311	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051314	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1005 10051315	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051316	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051318	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051322	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051323	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051326	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051331	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051332	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051335	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051340	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051341	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051343	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051345	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051346	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051349	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1005 10051350	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051354	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051356	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051357	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051358	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051361	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051362	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051363	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051364	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051365	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051366	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051368	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051369	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051370	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051371	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1005 10051377	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051378	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051380	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051381	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051385	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051386	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051390	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1005 10051393	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051394	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051396	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051397	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051398	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051400	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1006 10061070	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1006 10061099	Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1006 10061173	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1006 10061176	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071095	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071337	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071340	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071341	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071342	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071350	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071352	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071353	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071358	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071362	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071363	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071365	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071366	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071367	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1007 10071368	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071369	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071370	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071373	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071374	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071376	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071377	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071378	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071380	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071381	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071382	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071385	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071386	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071387	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071388	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1007 10071389	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071390	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071391	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071392	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071397	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071398	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071399	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071400	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071401	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071402	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071403	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071404	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071405	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071406	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071407	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1007 10071408	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071410	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071416	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071418	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071419	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071420	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071421	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071422	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071423	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071424	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071425	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071426	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071427	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071431	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071433	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1007 10071434	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071435	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071436	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071438	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071439	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071440	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071441	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071442	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071443	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081492	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081529	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081598	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081600	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081606	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081611	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081612	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081617	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081618	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081620	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081623	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081628	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081629	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1008 10081630	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081631	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081632	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081633	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081637	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081638	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081643	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081647	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081648	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081649	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081653	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081654	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081655	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081657	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081659	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1008 10081663	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081664	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081665	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081668	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081669	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081670	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081672	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081673	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081674	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081675	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081676	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081677	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081678	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081680	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081682	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1008 10081683	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081688	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081692	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081693	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081695	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081696	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081698	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081700	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081703	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081704	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081706	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081710	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081712	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081713	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081715	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1008 10081716	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081717	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081719	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081720	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081721	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081722	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081727	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081728	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081731	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081733	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081736	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081737	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081738	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081739	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081741	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1008 10081742	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081743	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081744	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091203	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091206	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091207	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091210	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091211	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091214	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091217	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091219	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091222	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091224	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091225	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091228	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1009 10091230	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091232	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091235	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091236	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091239	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091241	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091242	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091243	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091244	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091252	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091253	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091254	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091255	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091256	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091257	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1009 10091258	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091259	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111039	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111070	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111175	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111184	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111186	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111190	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111193	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1011 10111195	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111199	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111203	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111210	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111211	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111212	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111213	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111214	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111215	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111216	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111219	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111220	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111222	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111224	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111227	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1011 10111228	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111232	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111233	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111234	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111235	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111236	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111237	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1012 10121001	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1012 10121103	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1012 10121163	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131017	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131034	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131040	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131138	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131216	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131426	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131544	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131628	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131660	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131670	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131677	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131681	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131682	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1013 10131693	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131710	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131713	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131716	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131720	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131721	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131722	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131724	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131733	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131734	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131736	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131737	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131738	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131739	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131740	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131744	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131745	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131746	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1013 10131748	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131749	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131752	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131756	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131757	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131759	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131760	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131761	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131762	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131763	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131767	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1013 10131769	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131770	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131771	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131772	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131774	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131777	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131778	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131779	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131780	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131783	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131785	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131790	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131791	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131792	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131793	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1013 10131794	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131796	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131797	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131800	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131801	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131802	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131803	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131804	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131806	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131807	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131808	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131809	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131810	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131811	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131813	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1013 10131815	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131817	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151134	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151199	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151245	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151246	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151248	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151249	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151250	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151252	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151254	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151255	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151256	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151257	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151259	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1015 10151260	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151261	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151262	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151263	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151265	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151266	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151267	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151268	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161047	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161087	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161126	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161167	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161306	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161312	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161313	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161317	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161321	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161328	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161333	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161341	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161342	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161345	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161346	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1016 10161347	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181025	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181028	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181036	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181054	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181142	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181165	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181186	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181266	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1018 10181310	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181311	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181313	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181314	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181315	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181320	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181323	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181324	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181326	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181327	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181329	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181333	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181334	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181335	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181336	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1018 10181337	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181338	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181340	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181341	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181342	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181344	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181345	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181346	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181347	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181349	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181351	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181352	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181353	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191098	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191166	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1019 10191254	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191264	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191276	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191279	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191280	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191281	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191288	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191289	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191290	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191292	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191293	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191295	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191296	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191301	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191304	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1019 10191305	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191306	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191312	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191315	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191318	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191321	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1021 10211252	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1024 10241002	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1024 10241004	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241006	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241009	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241014	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241015	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241021	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241023	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241032	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241033	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241039	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241040	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241042	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241044	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241046	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241054	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1024 10241055	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241061	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241066	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241067	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241071	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241072	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241074	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241078	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241084	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241085	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241091	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241094	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241100	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241102	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241104	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1024 10241108	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241129	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1024 10241131	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1024 10241132	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1027 10271105	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1027 10271215	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1027 10271216	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281026	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1028 10281072	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281256	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281257	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281258	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281259	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281261	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281262	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281265	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1028 10281267	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281269	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281271	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281274	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281275	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281276	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281279	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281280	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281282	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281284	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281285	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281286	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281287	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281290	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281291	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1028 10281294	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1030 10301152	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1030 10301153	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1030 10301154	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1030 10301155	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361011	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361117	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361125	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361126	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361127	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361128	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361129	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361131	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361135	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361137	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1036 10361141	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361144	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361145	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371068	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371077	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371078	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371319	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371337	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371342	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371347	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371349	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371350	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371351	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371352	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371353	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1037 10371355	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371357	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371358	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371359	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371360	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1038 10381057	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1038 10381061	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1039 10391021	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391080	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391178	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391196	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391198	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391199	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391200	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391203	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391205	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1039 10391207	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391208	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391209	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391212	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391214	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391218	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391220	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391222	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391224	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391225	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391226	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391232	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391233	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391234	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391235	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1039 10391237	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391239	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391240	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391241	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391242	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1042 10421069	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1042 10421250	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1042 10421251	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1042 10421253	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1042 10421264	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1042 10421265	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1042 10421266	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1042 10421267	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441001	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441015	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441028	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441029	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1044 10441031	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441034	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441037	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441045	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441048	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441050	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441052	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441054	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441060	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441063	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441068	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441071	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441076	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441079	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441088	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1044 10441089	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441165	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441185	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441186	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441187	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441188	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441190	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441191	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441192	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441193	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441197	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441198	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441199	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441200	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441203	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1044 10441204	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441207	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441210	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441211	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441212	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441213	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441215	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441218	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441219	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441224	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441227	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461040	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461093	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461099	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461140	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461285	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1046 10461295	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461297	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461298	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461302	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461303	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461304	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461306	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461307	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461308	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461311	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461312	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461313	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461314	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461315	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461318	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461319	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461321	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461323	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461324	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461325	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461327	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461329	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461330	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1046 10461331	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461332	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461333	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461334	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461336	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461337	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461338	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461339	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461340	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471176	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471221	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471314	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471319	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471321	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471322	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471325	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471326	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471327	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471328	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471329	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471331	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471332	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1052 10521054	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1052 10521057	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1052 10521058	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1052 10521064	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1052 10521080	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1052 10521139	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1052 10521143	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1052 10521167	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541022	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1054 10541023	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541033	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1054 10541055	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541064	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541138	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541150	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541190	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1054 10541192	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541193	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541197	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541200	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541201	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541203	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541204	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541206	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541207	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541208	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541212	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541214	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541215	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1055 10551145	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1055 10551244	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1055 10551245	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1055 10551246	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1055 10551247	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1055 10551249	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561013	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561027	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561097	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561098	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561129	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561146	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561152	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561192	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561193	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561194	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561195	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561226	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561271	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561293	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561300	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561316	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561317	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1056 10561320	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561352	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561354	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561361	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561372	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561384	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561392	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561394	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561395	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1056 10561396	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561400	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561402	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561403	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561414	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561421	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561422	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561445	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1056 10561452	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561467	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1056 10561474	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561475	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561476	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561477	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561480	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561482	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561484	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561488	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561489	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561490	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561491	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561494	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561495	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561499	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561503	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1056 10561505	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561506	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561507	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561508	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561511	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561512	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561513	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561514	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561516	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561525	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561526	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561528	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561529	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561531	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561532	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1056 10561533	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561534	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561539	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561540	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561541	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561542	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561543	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561544	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561545	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561547	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561548	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561549	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561550	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561553	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561554	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1056 10561555	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561558	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561559	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561560	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561562	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561563	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561564	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561565	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561566	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561567	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561569	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561570	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561572	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561575	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561576	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1056 10561579	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561581	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561582	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561583	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561585	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561586	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561587	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561588	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561590	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561591	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561592	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561593	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561594	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561595	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561596	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1056 10561599	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561600	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561601	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561602	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561606	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561608	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561609	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561610	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561611	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561612	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561613	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561614	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561617	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561618	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561621	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1056 10561622	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561623	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561626	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561627	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561629	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561632	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561633	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561634	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561635	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561636	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561638	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561639	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561642	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561643	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571031	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571129	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571211	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571212	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571215	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571248	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571268	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571279	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571288	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571301	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571304	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571305	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571312	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571314	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571317	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571318	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571319	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571320	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571322	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571324	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571325	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571328	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1057 10571329	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571331	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571332	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571333	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571336	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571337	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571338	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571339	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571340	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571341	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571342	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571343	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571344	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571345	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571347	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1057 10571348	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571352	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571353	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571355	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571356	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571357	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571358	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571362	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661198	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661203	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661321	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661322	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661331	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661332	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661333	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661337	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661338	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661340	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661342	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661344	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661345	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661346	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661348	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1066 10661355	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661360	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661363	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661364	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661366	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661372	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661379	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661386	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661388	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661389	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661390	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1068 10681002	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681006	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681010	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681011	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681016	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681021	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681024	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681027	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1068 10681034	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681035	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681042	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681046	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681053	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681058	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681060	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681061	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681072	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681073	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681077	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681081	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1071 10711008	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711095	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1071 10711185	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711211	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711224	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711227	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711229	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711230	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711231	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711232	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711233	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711234	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711235	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711236	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711237	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711239	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711241	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1071 10711242	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711244	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711246	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711247	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711249	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711250	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1072 10721051	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1073 10731038	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771243	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771245	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771246	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771247	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771248	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771250	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771253	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1077 10771254	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771258	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771260	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771261	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771262	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771268	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771269	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771272	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791004	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791058	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791079	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791082	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791130	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1079 10791135	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791143	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791162	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791252	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1079 10791253	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791267	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791305	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791311	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791313	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791315	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791316	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1081 10811071	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1081 10811105	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821013	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821077	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821078	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821196	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821197	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821199	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821201	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821202	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821203	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821204	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821207	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821208	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821210	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1082 10821211	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821212	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821215	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821216	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821217	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821218	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821220	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821221	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821224	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831029	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831060	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831141	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831152	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831197	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831270	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831271	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1083 10831272	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831273	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831276	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831278	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831279	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831281	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831282	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831284	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841035	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841057	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841118	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841272	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841479	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841484	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841486	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841488	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841489	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841492	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841493	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841494	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841495	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841496	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841499	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1084 10841500	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841502	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841503	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841506	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841509	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841511	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841512	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841513	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841514	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841517	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841518	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841519	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841520	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841521	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841526	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1084 10841530	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841532	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841533	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841535	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841536	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841537	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1085 10851245	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1085 10851286	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1085 10851332	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1085 10851359	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1085 10851373	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1085 10851374	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1085 10851375	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871089	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871186	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871209	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871336	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871354	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871356	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871531	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871541	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871543	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871544	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1087 10871545	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871550	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871551	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871552	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871553	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871554	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871555	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871556	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871557	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871558	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871562	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871563	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871565	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871568	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871571	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1087 10871572	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871573	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871576	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871579	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871581	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871582	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871583	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871584	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871586	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871588	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871593	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871594	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871595	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871596	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871597	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1087 10871599	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871601	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1088 10881045	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1088 10881077	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1088 10881080	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1088 10881255	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1088 10881256	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1088 10881258	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1088 10881259	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1089 10891076	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1089 10891158	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1089 10891182	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1089 10891311	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1089 10891346	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1089 10891351	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901068	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901136	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901245	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901334	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1090 10901379	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901498	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901502	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901503	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901507	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1090 10901508	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901509	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901510	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901513	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901516	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901517	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901518	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901520	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901524	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901526	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901527	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901528	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901529	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901530	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901535	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1090 10901536	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901537	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901538	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901539	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901540	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901543	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901544	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901546	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901547	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901548	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901550	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901551	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901557	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901558	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901559	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1090 10901565	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901566	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911005	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1091 10911008	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1091 10911014	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1091 10911015	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1091 10911039	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911077	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911083	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911130	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1091 10911232	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911291	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911352	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911358	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911366	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911368	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911371	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911372	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911373	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911375	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911378	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911379	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911380	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911381	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911382	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911383	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1091 10911384	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911385	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911386	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921080	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921128	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921175	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921245	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921246	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921247	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921248	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921249	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921260	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921271	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921272	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921274	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1092 10921276	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931055	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931058	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1093 10931065	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931072	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931094	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931177	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931178	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931179	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931180	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931183	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931185	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931186	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931187	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1093 10931188	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931194	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931195	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931196	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931197	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931199	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931200	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931201	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931202	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931203	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931204	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931205	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931208	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931209	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931210	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1093 10931211	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931214	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931215	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931216	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931217	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931218	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931219	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931222	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931223	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931224	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931226	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941155	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941179	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941181	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941182	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1094 10941186	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941188	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941189	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941192	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951056	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951110	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951124	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951141	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1095 10951144	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951168	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951173	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951197	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951208	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951241	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951281	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951284	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951290	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951291	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951292	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951293	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951294	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951296	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951298	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951299	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1095 10951301	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951304	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951305	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951306	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951307	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961031	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1096 10961081	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1096 10961141	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961276	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961287	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961288	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961321	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961344	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961345	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961379	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961387	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961388	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961390	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1097 10971085	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1097 10971120	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1098 10981001	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1098 10981029	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1098 10981155	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1098 10981168	Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria.
	C4591001 1098 10981189	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1098 10981200	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1098 10981219	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1098 10981258	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1098 10981259	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1098 10981260	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1098 10981262	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1098 10981263	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1098 10981265	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1098 10981266	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1101 11011021	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1101 11011024	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1101 11011111	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1101 11011113	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1101 11011114	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1101 11011115	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1101 11011118	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1107 11071018	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1107 11071160	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1107 11071162	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1107 11071178	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091059	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091068	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091127	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091234	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091335	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091391	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091406	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091414	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091417	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091422	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091478	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091515	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091518	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091522	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091526	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091547	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 110911091556	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 111011101006	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 111011101038	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 111011101039	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 111011101069	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 111011101072	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 111011101085	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 111011101110	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1110 11101154	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101155	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101156	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101229	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101247	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101250	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101283	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101290	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101333	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101342	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101354	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101356	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101360	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101361	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101365	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1110 11101371	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101372	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101374	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101375	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101377	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111064	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111099	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111104	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111105	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1111 11111139	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111192	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111200	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111203	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121058	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1112 11121101	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121192	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121229	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121266	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121270	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121286	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121307	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121310	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121313	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121315	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1112 11121317	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121318	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121319	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121322	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121323	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121324	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121326	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121328	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121331	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121332	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121333	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121335	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121339	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121341	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121342	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1112 11121343	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121345	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121346	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121351	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1114 11141037	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1114 11141065	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1116 11161015	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1116 11161143	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1116 11161172	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1116 11161226	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1116 11161292	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1117 11171070	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1117 11171138	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1117 11171180	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1117 11171184	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1117 11171186	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1117 11171190	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1117 11171196	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1117 11171197	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181110	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181111	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181112	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181115	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181116	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181117	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181121	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181122	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201013	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201038	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201085	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201104	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201249	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201252	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201315	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201320	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201322	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201326	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201331	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201334	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201337	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201339	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201340	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201342	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201343	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1120 11201346	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201348	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201352	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201356	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201357	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201363	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201364	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201367	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201371	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201386	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201388	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201392	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201393	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201395	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201398	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1120 11201404	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201405	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201406	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201407	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201409	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201416	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201417	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201418	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201420	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201425	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201427	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201430	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201431	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201433	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1121 11211025	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

### 16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1122 11221006	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1122 11221052	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1122 11221053	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1122 11221059	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231027	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231144	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231154	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231168	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231208	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231263	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231290	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231298	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231313	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231377	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231381	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231382	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231383	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231384	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231386	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231387	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231389	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231392	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1123 11231395	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231397	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231398	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231399	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231403	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231404	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231405	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231407	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231408	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231409	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231410	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231411	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1124 11241003	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1124 11241049	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1124 11241084	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1124 11241100	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1125 11251019	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251148	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251159	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251160	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251237	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251238	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1126 11261053	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1126 11261074	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1126 11261200	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1126 11261201	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1126 11261202	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1126 11261203	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1127 11271022	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1127 11271099	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1128 11281012	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1128 11281093	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1128 11281126	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1128 11281146	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1128 11281368	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291061	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291165	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291229	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291238	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291244	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291245	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1129 11291249	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291252	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301081	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301082	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301083	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301084	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301085	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301086	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301087	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301088	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301089	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301090	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301091	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301092	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301093	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1130 11301094	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301097	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301099	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311024	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311193	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311243	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311246	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311252	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311253	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311254	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311257	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311260	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331037	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331042	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331052	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1133 11331059	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331087	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331120	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331122	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331138	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331162	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331170	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331207	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1133 11331291	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331295	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331316	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331338	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331341	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331346	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331509	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331510	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331512	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331521	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331522	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331523	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331524	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331525	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331526	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331527	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1133 11331528	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331529	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331530	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331531	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331532	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331533	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331534	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331535	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331536	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331537	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331538	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331539	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331540	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331541	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331542	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1133 11331543	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331544	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331545	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331546	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331547	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331548	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331549	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331550	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331551	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331552	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331553	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331554	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331555	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331556	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331557	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1133 11331558	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331559	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331560	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331561	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331562	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331563	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331564	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331565	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331566	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331567	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331568	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331569	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331570	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331571	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331572	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1133 11331573	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331574	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331575	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331577	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331578	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331579	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331580	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331581	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331582	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331583	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331584	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331585	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331586	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331587	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331588	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1133 11331589	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331590	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331591	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331592	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331593	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331594	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331595	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331596	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331598	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331600	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331601	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331602	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331603	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331604	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331605	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1133 11331606	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331609	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331610	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331612	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331613	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331614	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331615	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331616	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331617	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331618	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331619	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331621	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331622	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331624	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331625	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1133 11331626	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331627	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331628	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331629	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331630	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331631	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331632	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331633	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331634	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331635	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331636	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331637	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331638	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331639	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331640	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1133 11331641	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331642	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331643	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331644	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331645	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331646	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331647	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331648	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341033	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341153	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341174	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341177	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341228	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341397	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341413	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341416	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1134 11341417	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341420	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341421	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341424	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341425	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341426	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341428	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341433	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341435	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341436	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341437	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341438	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351061	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351132	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351199	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351200	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351212	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351389	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351420	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351428	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351430	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351440	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351441	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351442	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351443	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351444	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351445	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351446	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351448	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351449	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1135 11351450	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351451	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351452	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351453	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351454	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351455	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351456	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351457	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351458	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351459	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351460	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351461	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351462	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351463	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351464	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1135 11351465	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351466	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351467	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351468	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351469	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351470	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351471	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351472	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351473	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351474	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351475	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351476	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351477	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351479	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351480	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1135 11351482	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351483	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351484	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351485	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351486	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351487	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351488	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351489	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351490	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351491	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351492	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351493	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351494	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351495	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351496	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1135 11351497	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351498	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351499	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351500	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351501	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351502	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351503	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351505	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351506	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351508	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351509	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351510	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351511	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351512	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351513	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1135 11351514	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351516	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351517	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351518	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351519	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351520	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351521	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351522	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351523	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351524	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351525	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351526	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351527	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351528	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351529	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1135 11351530	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351531	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351532	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351533	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351534	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351535	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351536	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351537	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351538	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351539	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351540	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351541	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351542	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351543	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351544	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1135 11351545	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351546	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351547	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351548	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351549	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351550	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351551	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351552	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351553	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351554	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351555	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351556	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351557	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351558	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351559	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1135 11351560	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351561	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351562	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351563	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351564	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351565	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351566	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351567	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351568	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351569	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351571	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351572	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351573	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361043	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361045	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1136 11361067	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361072	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361073	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361076	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361082	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361083	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361084	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361087	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361090	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361091	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361092	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361095	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361098	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361099	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361100	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1136 11361101	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391102	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391106	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391109	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391110	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391112	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391113	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391114	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391116	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391117	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391119	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391120	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391125	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391127	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401285	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1140 11401290	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401298	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401299	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401301	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401303	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401304	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401306	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401308	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401309	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401310	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401311	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401314	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411011	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1141 11411014	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1141 11411023	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1141 11411065	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1141 11411096	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411127	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1141 11411146	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411164	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411166	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411179	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411249	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411260	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411262	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411263	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411264	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1141 11411265	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411266	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411267	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411269	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411270	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421084	Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria.
	C4591001 1142 11421286	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421287	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1142 11421289	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421290	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421292	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421293	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421295	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421298	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421299	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421300	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421303	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421306	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421307	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421308	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421310	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1145 11451063	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1145 11451108	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1145 11451110	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1145 11451112	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1145 11451115	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461010	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461267	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461268	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461269	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461270	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1146 11461271	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461272	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461273	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461274	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461275	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461276	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461277	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461278	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461279	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461280	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461281	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461282	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461283	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461284	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461285	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1146 11461286	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461287	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461288	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461289	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461290	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461291	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461292	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461293	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461294	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461295	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461296	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461297	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461298	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461299	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461300	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1146 11461301	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461302	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461303	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461304	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461305	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461306	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461307	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461308	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461309	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461310	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461311	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461312	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461313	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461314	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461315	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1146 11461316	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461317	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461318	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461319	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461320	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461321	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461322	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461323	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461324	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461325	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461326	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461327	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461328	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461329	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461331	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1146 11461332	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461333	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461334	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461335	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461336	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461337	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461338	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461339	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461340	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461341	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461342	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461343	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461344	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461345	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461346	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1146 11461347	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461348	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461349	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461350	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461351	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461352	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461353	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461354	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461355	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461356	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461357	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461358	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461359	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461360	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461361	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1146 11461363	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461364	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461365	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461366	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461367	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461368	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461369	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461370	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461371	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461372	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461373	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461374	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461375	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461376	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461377	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1146 11461378	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461379	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461380	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461381	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461382	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461384	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461385	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461386	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461387	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461388	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461389	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461390	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461391	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461393	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461394	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1146 11461395	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461397	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461398	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1146 11461399	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1147 11471035	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1147 11471212	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491005	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491031	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491065	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491066	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491067	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491088	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491172	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491209	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491230	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1149 11491328	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491329	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491331	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491332	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491334	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491335	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491337	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491339	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491340	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491342	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491344	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501137	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501138	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501139	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501140	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1150 11501141	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501142	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501144	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1150 11501145	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521030	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521034	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521085	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521477	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521499	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521517	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521519	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521520	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521521	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521529	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521533	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1152 11521541	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521549	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521551	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521552	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521557	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521560	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521566	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521568	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521569	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521570	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521571	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521575	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521577	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521583	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521584	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1156 11561006	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561015	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1156 11561033	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561200	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561229	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561230	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561231	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1156 11561235	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561239	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561251	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561252	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561258	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561268	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561270	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561272	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561273	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561274	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561275	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561276	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561277	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561281	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561282	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1156 11561283	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561286	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561287	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561288	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561289	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561290	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561291	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561292	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561293	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561294	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571003	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571070	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571135	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571156	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571166	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1157 11571168	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571169	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571170	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571174	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571176	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1161 11611001	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611002	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611004	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611005	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611006	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611007	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611008	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611009	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611010	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1161 11611011	Dose 2 all-available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611014	Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611015	Dose 2 all-available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611016	Dose 2 all-available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611017	Dose 2 all-available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611018	Dose 2 all-available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611019	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611020	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611023	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611024	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611026	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611027	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611028	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1161 11611032	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611033	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611034	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611040	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611041	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1162 11621005	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621118	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1162 11621217	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621294	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621310	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621356	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621374	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621381	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621391	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621496	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1162 11621500	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621510	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621513	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621514	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621515	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621518	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621519	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621520	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621522	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621524	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621526	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621534	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621535	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621537	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621538	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1162 11621539	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621540	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621541	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621543	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621545	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621548	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621549	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621551	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621553	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621554	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621559	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621563	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621566	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621569	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621570	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1162 11621571	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621572	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621573	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621574	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621576	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621579	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621580	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621582	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621583	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621584	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621585	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1163 11631006	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631059	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1163 11631069	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1163 11631096	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1163 11631117	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631121	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631124	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631127	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631136	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631142	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631145	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1166 11661047	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1166 11661091	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1166 11661097	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1166 11661099	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1166 11661103	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1166 11661104	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1166 11661106	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1166 11661109	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1166 11661110	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1167 11671003	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1167 11671111	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 11671167	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 11681168	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 11681168	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 11681168	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 11681168	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 11681168	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 11681168	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 11681168	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1168 11681231	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1168 11681234	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1168 11681239	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1168 11681241	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1169 11691058	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701015	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701023	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701059	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701064	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1170 11701112	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701117	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701201	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701205	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701300	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701308	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701311	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701316	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701344	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1170 11701364	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701365	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701374	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701375	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701376	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701377	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701378	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701379	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701380	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701381	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1170 11701382	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701383	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701384	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701385	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701386	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701387	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701388	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701389	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701390	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701391	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701392	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701393	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701394	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701395	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701396	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1170 11701397	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701398	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701399	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701400	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701401	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701402	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701403	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701404	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701405	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701406	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701407	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701408	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701410	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701411	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701412	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1170 11701413	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701414	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701416	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701417	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701418	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701419	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701420	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701421	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701422	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701423	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701424	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701425	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701426	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701427	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701428	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1170 11701429	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701430	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701431	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701432	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701433	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701434	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701435	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701436	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701437	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701438	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701439	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701440	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701441	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701442	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701443	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1170 11701444	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701445	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701446	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701447	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701449	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701450	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701451	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701452	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701453	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701455	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701456	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701457	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701458	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701459	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701460	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1170 11701461	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701462	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701463	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701464	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701465	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701466	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701467	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701468	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701469	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701470	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701471	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701472	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701473	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701474	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701475	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1170 11701476	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701477	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701478	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701479	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701480	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701481	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701482	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701483	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701484	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701485	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701486	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701487	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701488	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701489	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701490	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1170 11701491	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701492	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701493	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701494	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701495	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701496	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701497	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701498	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701499	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701500	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701501	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711042	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711072	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711101	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711131	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711151	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1171 11711153	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711154	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711159	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711189	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711214	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711216	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711219	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711221	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711224	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711225	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711226	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711228	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711229	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711231	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1171 11711236	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711241	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711242	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711247	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711248	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711249	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711250	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711301	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1174 11741066	Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria.
	C4591001 1177 11771139	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771292	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771415	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1177 11771475	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771491	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771504	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771509	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771510	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771511	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771514	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771515	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1177 11771516	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771517	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771520	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771521	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771524	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771525	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771526	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771528	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771529	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771531	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771532	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771533	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771534	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771537	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771539	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1177 11771540	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771541	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771543	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771544	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771548	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771549	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771550	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771551	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771552	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771554	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771555	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771556	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771557	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771562	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771563	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1177 11771564	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771565	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1178 11781061	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1178 11781107	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1178 11781298	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1178 11781309	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1178 11781310	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1178 11781311	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1178 11781312	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1178 11781314	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1178 11781316	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791117	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791118	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791123	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791125	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791126	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791130	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791131	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791133	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791136	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791137	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791138	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791139	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1179 11791143	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791144	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791145	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791146	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791147	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791148	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791149	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791150	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791152	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791153	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791154	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851002	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851005	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851008	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851009	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1185 11851010	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851011	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851012	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851013	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851015	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851017	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851018	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851021	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851022	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851023	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851024	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851025	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851028	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851029	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851030	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1185 11851032	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851033	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851036	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851038	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851039	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851040	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851041	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851043	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851048	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851049	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851050	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851051	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851052	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851053	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851054	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1185 11851055	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851056	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851059	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851060	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851063	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851064	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851066	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851067	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941003	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941004	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941009	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941014	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941016	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941023	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941024	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1194 11941025	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941026	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941030	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941031	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941032	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941033	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941034	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941041	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941043	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941044	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941045	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941046	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941047	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941048	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941051	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1194 11941052	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941053	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941054	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941056	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941057	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941058	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941061	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941062	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941066	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941067	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941069	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941071	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941072	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941080	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941081	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1194 11941082	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941083	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941086	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941087	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941088	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941089	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941090	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941091	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941092	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941093	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941096	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941097	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941098	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941100	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941103	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1194 11941105	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941106	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951001	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951002	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951003	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951004	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951005	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951013	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951015	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951018	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951024	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951026	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951027	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951032	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951035	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1195 11951041	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951043	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951051	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951053	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951054	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951055	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951056	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951060	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1195 11951061	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951062	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951063	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951064	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951065	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951066	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951067	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951068	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951070	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951071	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951072	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951073	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951074	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951075	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951076	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1195 11951077	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951079	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951080	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951081	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951082	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951083	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951084	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951085	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951089	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951090	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951091	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951092	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951093	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951098	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951099	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1195 11951100	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951101	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951104	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951105	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951106	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951107	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951108	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951109	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951113	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951114	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951115	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951116	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951117	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951118	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951119	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1195 11951120	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951123	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951134	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951135	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951136	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951137	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951138	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951139	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951140	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951141	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951142	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951146	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951147	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951148	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951153	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1195 11951154	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951155	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951157	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951158	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971005	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971007	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971015	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971026	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971029	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971031	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971035	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971039	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971040	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971041	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971042	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971045	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971053	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971058	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971059	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971060	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971064	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971068	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971069	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1197 11971077	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971078	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971079	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971088	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971092	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971093	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971094	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971096	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1202 12021007	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1202 12021009	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1202 12021010	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1202 12021011	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031001	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031004	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031005	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1203 12031008	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031010	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031015	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031020	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031021	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031026	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031030	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031031	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031032	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031033	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031034	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031037	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031041	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031042	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031044	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1203 12031045	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031047	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031048	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031051	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031053	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031056	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031057	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031058	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031059	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031060	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031063	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031064	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031066	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031067	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031069	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1204 12041111	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041165	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041197	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041233	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041236	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041237	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041238	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041239	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1204 12041240	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041241	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041242	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041247	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041248	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041252	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041253	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041255	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041256	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041257	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041258	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041259	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041260	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041261	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041262	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1204 12041263	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041264	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041265	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041267	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041268	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041269	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041270	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041271	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041272	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041273	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041274	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041275	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041276	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041279	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041280	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1204 12041281	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041283	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041284	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041285	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041286	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041287	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041288	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041290	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041292	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041293	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041294	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1205 12051003	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1205 12051004	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1205 12051010	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1205 12051011	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 120512051012	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051013	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051014	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051015	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051017	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051021	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051022	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051023	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051024	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051025	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051026	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051027	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051028	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051029	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051030	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051032	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051033	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051034	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051035	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051036	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051041	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051042	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 120512051043	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051044	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051047	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120712071002	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120712071003	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120712071005	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120712071006	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120712071007	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071008	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071009	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071010	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071011	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071012	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071013	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071014	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1207 12071016	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071018	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071021	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071023	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071024	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071025	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071026	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071027	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071028	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071032	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071033	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071036	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071037	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071038	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071039	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1207 12071040	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071041	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071042	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071044	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071045	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071046	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071047	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071048	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071049	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071050	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071051	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071052	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081001	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081002	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081003	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1208 12081004	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081005	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081007	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081008	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081009	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081010	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081011	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081012	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081013	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081016	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081017	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081018	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081019	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081020	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081021	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 120812081022	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120812081023	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120812081024	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120812081025	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120812081026	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120812081027	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120812081028	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120812081029	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081030	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081031	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081032	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081033	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081034	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1209 12091001	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1209 12091002	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 120912091003	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120912091004	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120912091006	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120912091007	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120912091008	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120912091009	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120912091010	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120912091011	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1209 12091013	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1209 12091015	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1209 12091016	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1209 12091017	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1209 12091018	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1209 12091019	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1209 12091020	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1210 12101001	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101002	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101005	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101006	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101007	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101008	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101009	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101010	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101011	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101012	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101013	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101014	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101015	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101016	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101017	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1210 12101018	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101019	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101020	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101021	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101022	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101023	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101024	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101025	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101026	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101027	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101028	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101029	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101030	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101031	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101032	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1210 12101033	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101034	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101035	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101036	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101037	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101038	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101039	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101040	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101041	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101045	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101046	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101047	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101048	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121001	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121002	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1212 12121003	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121004	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121005	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121006	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121007	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121008	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121009	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121010	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121011	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121012	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121013	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121014	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121015	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121016	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121017	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1212 12121018	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121019	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121020	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121022	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131001	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131002	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131003	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131004	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131005	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131006	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131008	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131010	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131012	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131013	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131014	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1213 12131015	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131016	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131018	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131019	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131025	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131026	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131028	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131032	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131033	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131034	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131036	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141001	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141004	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141005	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141007	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1214 12141008	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141009	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141012	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141013	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141014	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141015	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141016	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141017	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141018	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141019	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141020	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141022	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141023	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141024	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141025	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1214 12141027	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141029	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141030	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141031	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171002	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171003	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171005	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1217 12171008	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171009	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171010	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171011	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171012	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171013	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171014	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171015	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171016	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171017	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171018	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171019	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171020	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171021	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171022	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1217 12171023	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171028	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171030	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171031	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171032	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171034	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171035	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171037	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171038	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171039	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171041	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171042	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171044	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171045	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1218 12181001	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 121812181003	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 121812181004	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 121812181005	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 121812181006	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 121812181007	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 121812181008	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 121812181009	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 121812181011	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1218 12181012	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1218 12181013	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1219 12191004	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1219 12191022	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1219 12191023	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1219 12191024	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1219 12191026	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1219 12191028	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1219 12191029	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1219 12191030	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201015	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201017	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201018	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201020	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201021	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201022	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201024	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201025	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201026	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201027	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201028	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201029	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1220 12201030	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201031	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201032	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201033	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201035	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201036	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1221 12211005	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1221 12211006	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1221 12211007	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1221 12211010	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1221 12211011	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1221 12211012	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1221 12211013	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1221 12211014	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1221 12211020	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1221 12211022	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1221 12211023	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231174	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231190	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231234	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231241	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231242	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1223 12231243	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231244	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231245	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231246	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231247	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231249	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231251	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231252	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231253	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231256	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231258	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231260	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231264	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231265	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1224 12241009	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1224 12241065	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12261072	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12261114	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12261380	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12261391	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12261409	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12261797	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12261894	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12261927	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1226 12261952	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262013	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262063	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262083	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262085	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262089	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262108	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262132	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262133	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262136	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262140	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262146	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262162	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262163	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262165	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1226 12262166	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262178	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262182	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262184	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262186	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262189	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262194	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262195	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262197	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262208	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262209	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262211	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262212	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262213	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262216	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1226 12262217	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262218	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262219	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262220	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262221	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262223	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262224	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262225	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262226	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262227	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262228	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262229	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262230	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262236	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262237	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1226 12262239	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262242	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262243	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262245	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262246	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262247	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262249	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262251	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262252	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262255	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1226 12262256	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262258	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262259	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262260	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262261	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262262	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262263	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262267	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262268	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262269	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262270	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262272	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1226 12262273	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262274	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262275	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262276	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262278	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262279	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262280	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262282	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262283	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262284	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262285	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262286	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262287	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262289	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262290	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1226 12262291	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262292	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262293	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262294	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262295	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262297	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262298	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262299	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262300	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262301	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262303	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262304	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262307	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262309	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262311	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1226 12262313	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262314	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262315	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262316	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262317	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262318	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262319	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262320	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262321	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262322	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262326	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262327	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262329	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262330	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262331	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1226 12262334	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262335	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262337	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262338	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262339	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262340	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262341	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262343	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262346	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262347	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262348	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262350	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262351	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262352	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262353	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1226 12262354	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262356	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262357	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1229 12291139	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1229 12291146	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1229 12291165	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1229 12291180	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1229 12291197	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1229 12291198	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1229 12291204	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1229 12291213	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1229 12291217	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1230 12301045	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1230 12301065	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1230 12301099	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1230 12301113	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1230 12301148	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1230 12301150	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1230 12301151	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311027	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311031	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311054	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311087	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311088	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12311125	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311147	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311189	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311191	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311195	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311200	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311301	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1231 12311356	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311374	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311391	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311402	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311409	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311420	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311431	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311441	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311443	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311473	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311499	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12311516	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311532	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311559	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311568	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1231 12311641	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311656	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311801	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311816	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311825	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311858	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311885	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12311894	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311911	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311926	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311991	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312052	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312077	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312176	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312244	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312284	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312320	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1231 12312326	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312334	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312339	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312361	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312365	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312372	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312375	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312403	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1231 12312426	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312435	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312439	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312451	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312483	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312559	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312577	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312594	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312623	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312660	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312752	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312763	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312805	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312848	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312868	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312916	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313006	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313068	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313069	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313098	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313115	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313125	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313175	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313207	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313211	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313225	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313289	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313357	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313376	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313395	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313428	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313429	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313443	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313449	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313454	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313456	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313459	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313467	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313469	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1231 12313479	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313483	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313486	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313487	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313492	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313497	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313498	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313501	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1231 12313505	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313506	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313508	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313509	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313510	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313512	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313514	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313515	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1231 12313516	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313517	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313518	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313519	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313527	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313528	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313533	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1231 12313534	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313537	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313541	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313542	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313546	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313551	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313553	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313554	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313556	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313564	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313567	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313592	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313622	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313657	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313662	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313709	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313758	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313869	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313892	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313939	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313967	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314134	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314179	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314205	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1231 12314266	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314290	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314314	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314381	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314385	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314416	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314492	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314502	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314525	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314580	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314590	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314679	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314700	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314713	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314738	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314848	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314857	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1231 12314923	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314984	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12315189	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12315204	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12315223	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12315269	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12315308	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12315322	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12315357	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12315429	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12315441	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12315518	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12315600	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12315681	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321015	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321033	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321100	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1232 12321101	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321142	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321175	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321213	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1232 12321219	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321220	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321233	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1232 12321244	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321249	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321250	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321287	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321293	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321299	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321305	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321310	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1232 12321318	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321330	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321332	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321337	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321343	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321344	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321348	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321351	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321352	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321354	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321356	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321359	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321361	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321362	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321364	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1232 12321366	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321370	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321371	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321373	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321374	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321376	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321377	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321378	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321380	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321382	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321384	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321385	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321386	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321391	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321393	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1232 12321394	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321395	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321396	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321397	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321400	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321401	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321402	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321404	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321406	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321408	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321412	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321413	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321414	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321415	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321416	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1232 12321417	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321419	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321420	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321421	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321422	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321423	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321424	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321425	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321426	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321427	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321428	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321429	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321430	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321431	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321433	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1232 12321434	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321435	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351027	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351071	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351167	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351169	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351174	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1235 12351175	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351187	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351188	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351189	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351190	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351191	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351192	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351193	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351195	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351196	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351197	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351200	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351207	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351208	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351209	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1235 12351212	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351214	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351215	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351217	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351218	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351219	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351222	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351223	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351224	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351225	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351226	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351228	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351230	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351231	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12411132	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12411144	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12411260	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12411273	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12411279	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1241 12411482	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12411688	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12411695	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12411766	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12411993	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412026	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412172	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412174	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412177	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412181	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412182	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412188	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412192	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412193	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412194	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412195	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412197	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412198	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412199	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412201	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412202	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412206	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412207	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412208	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412209	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412210	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412212	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412213	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412214	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412216	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412217	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412218	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412221	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412222	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412223	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412225	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412226	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412227	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412228	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412229	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412232	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412233	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412235	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412236	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412237	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412239	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412240	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412243	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412244	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412245	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412246	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412247	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412248	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412249	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412252	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412253	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412254	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412255	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412256	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412257	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412258	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412259	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412260	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412261	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412262	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412264	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412267	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412268	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412269	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412270	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412271	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412274	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412275	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412276	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412277	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412278	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412279	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412280	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412281	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412282	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412283	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412284	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412285	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412288	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412289	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412290	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412291	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412293	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412294	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412295	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412296	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412299	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412301	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412303	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412304	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412306	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412307	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412308	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412311	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412312	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412313	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412314	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412315	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412317	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412320	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412321	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412322	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412323	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412324	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412327	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412328	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412329	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412330	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412331	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412332	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412333	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412334	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412335	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412336	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412337	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412338	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412339	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412341	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412342	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412343	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412344	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412345	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412346	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412347	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412348	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412350	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412351	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412352	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412353	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412354	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412355	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412357	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412358	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412360	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412361	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412362	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412363	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412364	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412365	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412366	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412367	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412368	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412369	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412370	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412371	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412373	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412374	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412375	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412377	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412378	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412379	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412380	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412381	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412382	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412383	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412385	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412386	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412387	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412389	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412390	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412391	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412392	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412393	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412394	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412395	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412396	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412397	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412398	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412399	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412400	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412401	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412402	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412403	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412404	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412405	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412406	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412407	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412409	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412410	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412411	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412412	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412413	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412414	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412415	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412416	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412417	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412418	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412419	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412420	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412421	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412422	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412423	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412424	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412425	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412426	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412427	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412428	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412429	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412430	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412431	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412432	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412433	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412434	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412435	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412436	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412437	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412438	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412439	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412440	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412441	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412442	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412443	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412444	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412445	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412447	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412448	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412449	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412450	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412451	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412452	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412453	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412454	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412455	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412456	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412457	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412458	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412459	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412460	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412461	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412462	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412463	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412464	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412465	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412466	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412467	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412468	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412470	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412471	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412472	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412473	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412475	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412476	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412477	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412478	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412479	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412480	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412482	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412485	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412486	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412490	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412491	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412493	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412494	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412495	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412498	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412500	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412501	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412502	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412504	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412505	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412506	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412507	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412508	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412509	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412510	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412512	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412513	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412515	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412516	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412517	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412518	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412519	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412523	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412525	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412527	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412528	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412529	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412530	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412532	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412534	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412535	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412537	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412539	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412540	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412543	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412544	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412546	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412547	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412548	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412549	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412550	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412551	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412552	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412553	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412554	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412556	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412557	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412558	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412559	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412560	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412561	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412562	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412563	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412564	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412565	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412566	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1246 12461025	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1247 12471054	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1247 12471149	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1247 12471151	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1248 12481005	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1248 12481018	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1248 12481025	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1248 12481046	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1248 12481048	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1248 12481060	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1248 12481110	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1248 12481169	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1248 12481170	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1248 12481175	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1248 12481199	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1248 12481218	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
	C4591001 1248 12481252	Evaluable efficacy (7 Days) Dose 2 all-available efficacy	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1248 12481253	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511095	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511207	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511241	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511242	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511246	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511247	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511252	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511253	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511254	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511255	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511256	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511259	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1251 12511262	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541005	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541008	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541023	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541027	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541029	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541030	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541033	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541035	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541038	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541040	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541116	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541142	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541154	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541185	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541187	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541188	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541189	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541190	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1254 12541193	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541194	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541199	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541201	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541202	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541204	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541208	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541210	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541211	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1258 12581062	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1258 12581065	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1258 12581066	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1258 12581067	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1258 12581069	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1258 12581070	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 125812581071	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 125812581072	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 125812581073	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 125812581074	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 125812581075	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 126012601002	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 126012601005	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 126012601006	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 126012601009	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 126012601013	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1260 12601014	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1260 12601016	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1260 12601017	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1260 12601029	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1260 12601032	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1260 12601036	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1260 12601049	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1260 12601070	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1260 12601126	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1261 12611054	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1264 12641209	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641210	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641211	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641212	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641213	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641215	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641216	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641218	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641221	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641225	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641226	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641227	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641228	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1269 12691081	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1270 12701056	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 4444 44441007	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441025	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441043	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441044	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441048	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441079	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441134	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441135	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441179	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441273	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441522	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441560	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441569	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441572	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441818	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 4444 44441860	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441912	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441931	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441938	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441951	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441979	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442058	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442059	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442062	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442065	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442069	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 4444 44442070	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442071	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442072	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442077	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442080	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442081	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442084	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442085	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442086	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442087	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442088	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442090	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442091	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 4444 44442093	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442095	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442100	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442101	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442105	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442107	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442113	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442114	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442115	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442117	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442119	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442131	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442135	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442140	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 4444 44442142	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442151	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442156	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442157	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442159	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442160	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442161	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442162	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442165	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442168	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442170	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442174	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442188	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442190	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 4444 44442194	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442196	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442197	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442199	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442205	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442212	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442215	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442216	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442217	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442218	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442219	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442226	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442232	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442233	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442236	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442237	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442241	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442245	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442249	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442250	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442253	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442255	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442256	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442262	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442263	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442268	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 4444 44442269	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442270	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442274	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442277	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442278	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442279	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442281	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442283	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442284	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442285	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442287	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442288	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442292	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 4444 44442293	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442294	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442297	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442298	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442301	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442303	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442304	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442306	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442307	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442308	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442310	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442313	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442314	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442315	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
>55	C4591001 4444 44442319	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442322	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1003 10031120	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1005 10051214	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051247	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051249	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
C4591001 1005 10051250	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.	
	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).	
C4591001 1005 10051252	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.	
	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).	
C4591001 1005 10051253	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.	

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051256	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051262	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051263	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051265	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051266	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051271	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051275	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1005 10051278	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051282	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051284	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051286	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051287	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051293	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051296	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051298	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051299	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051300	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051303	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051304	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051306	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051307	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051309	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1005 10051312	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051313	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051319	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051320	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051321	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051324	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051325	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051327	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051329	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051330	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051333	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051334	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051336	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051337	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051338	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1005 10051342	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051344	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051347	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051348	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051351	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051353	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051355	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051360	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051367	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051372	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051373	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051374	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051375	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051379	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051382	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1005 10051387	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051389	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051391	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051392	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051395	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051399	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1005 10051402	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1006 10061020	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1006 10061177	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1006 10061178	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071105	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1007 10071114	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071213	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071308	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071315	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071324	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1007 10071327	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071333	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071335	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071336	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071338	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071343	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071344	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071345	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071346	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071347	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071348	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071349	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071351	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071354	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071355	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1007 10071356	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071357	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071359	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071360	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071364	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071371	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071372	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071375	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071379	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071383	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071384	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071393	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071396	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071411	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071412	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1007 10071430	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1007 10071432	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081599	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081601	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081602	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081603	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081613	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081614	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081615	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081616	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081619	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081621	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081622	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081624	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081625	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1008 10081626	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081627	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081634	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081635	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081636	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081639	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081640	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081641	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081642	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081644	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081645	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081646	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081650	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081651	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081652	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1008 10081656	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081658	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081660	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081661	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081662	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081666	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081667	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081671	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081679	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081681	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081684	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081685	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081686	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081687	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081689	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1008 10081690	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081691	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081694	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081697	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081699	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081701	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081702	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081705	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081707	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081708	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081709	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081711	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081714	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081718	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081723	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1008 10081724	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081725	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081726	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081729	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081730	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081732	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081734	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081735	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1008 10081740	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091020	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091089	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1009 10091157	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111028	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111029	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111085	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111086	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111181	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111189	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111192	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111194	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111196	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111200	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111201	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111202	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111204	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1011 10111208	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111209	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111217	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111218	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111221	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111223	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111225	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111226	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111229	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111230	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1011 10111231	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1012 10121139	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1012 10121149	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131097	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131176	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131186	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1013 10131192	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131679	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131692	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131694	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131698	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131699	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131705	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131706	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131712	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131714	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131715	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131725	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131726	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131728	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131735	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1013 10131741	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131742	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131743	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131747	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131750	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131751	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131753	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131754	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131755	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131758	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131764	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131765	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131766	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131768	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131773	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1013 10131775	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131776	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131781	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131782	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131784	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131786	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131787	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131789	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131795	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131798	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131799	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131805	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131812	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131814	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1013 10131816	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1015 10151244	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151247	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151251	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151253	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1015 10151258	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161026	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161162	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161166	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1016 10161282	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1018 10181328	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181332	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181339	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1018 10181348	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191201	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191261	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191277	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191278	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191282	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191283	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191284	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191285	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191286	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191287	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191291	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1019 10191297	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191298	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191299	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191302	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191303	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191307	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191309	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191310	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191311	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191313	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191314	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191316	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191317	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191319	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191320	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1019 10191322	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1019 10191323	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1021 10211221	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1021 10211251	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1022 10221015	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1022 10221057	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1022 10221150	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1024 10241003	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241010	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241018	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241019	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241031	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241037	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241041	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241049	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241057	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241059	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241065	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241068	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241077	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241081	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241083	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241087	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241096	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241097	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1024 10241125	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
	C4591001 1024 10241126	Evaluable efficacy (7 Days) Dose 2 all-available efficacy	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not complete 2 vaccination doses.
	C4591001 1024 10241127	Evaluable efficacy (7 Days) Dose 2 all-available efficacy	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not complete 2 vaccination doses.
	C4591001 1024 10241128	Evaluable efficacy (7 Days) Dose 2 all-available efficacy	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1). Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1024 10241130	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1024 10241133	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1024 10241134	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1027 10271206	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281252	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281264	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281266	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281268	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281270	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281272	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281273	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281277	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281278	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281283	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281288	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1028 10281289	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281292	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281293	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281295	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1028 10281296	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1030 10301149	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1030 10301151	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1030 10301156	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1030 10301157	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1030 10301158	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361120	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361124	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361130	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361132	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361133	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1036 10361134	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361138	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361139	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361140	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361142	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1036 10361143	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371057	Dose 1 all- available efficacy  Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not receive at least 1 vaccination.  Did not complete 2 vaccination doses.  Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1037 10371117	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371195	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371275	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371303	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371334	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371335	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371338	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371339	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371345	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371354	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1037 10371356	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1038 10381056	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391019	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1039 10391192	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391197	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1039 10391201	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391202	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391206	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391211	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391213	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391217	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391221	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391227	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391228	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391229	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391230	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391231	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1039 10391238	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1042 10421010	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1042 10421263	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1042 10421268	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1042 10421269	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441002	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441004	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441007	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441010	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441016	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441018	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441032	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441036	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441041	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441047	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441049	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1044 10441055	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441062	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441067	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441073	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441075	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441080	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441083	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441085	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441090	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441092	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441093	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441094	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1044 10441113	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1044 10441116	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441182	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441184	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441189	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441194	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441195	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441196	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441201	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1044 10441202	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441205	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441206	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441208	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441209	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441214	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441216	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441217	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441220	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441221	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441222	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441223	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441225	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1044 10441226	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461084	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461126	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1046 10461245	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461259	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461278	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461279	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461282	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461299	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461301	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461305	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461309	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461310	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461316	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461317	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461320	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461322	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461326	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1046 10461328	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1046 10461335	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471122	Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1047 10471228	Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1047 10471252	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471300	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471315	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471320	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471323	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471324	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1047 10471330	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1052 10521020	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1052 10521062	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1052 10521142	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541024	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1054 10541071	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541175	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541186	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541194	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541195	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541196	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541198	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541199	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541202	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1054 10541205	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541209	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541210	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541211	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1054 10541213	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1055 10551039	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1055 10551248	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561015	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1056 10561018	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561032	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561034	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561078	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561079	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561095	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561099	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561120	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561123	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1056 10561229	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561232	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561275	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561276	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561298	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561301	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561302	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561303	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561306	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561337	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1056 10561353	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561371	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561381	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561399	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561404	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561409	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561415	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561426	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561455	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561463	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561479	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561481	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561483	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561485	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561486	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561492	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561496	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1056 10561497	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561498	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561500	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561501	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561502	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561509	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561515	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561523	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561524	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561527	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561537	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561538	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561546	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561551	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561552	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1056 10561556	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561557	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561561	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561571	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561573	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561574	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561577	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561578	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561580	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561584	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561589	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561597	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561598	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561603	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561604	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1056 10561605	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561607	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561615	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561616	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561619	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561620	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561625	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561628	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561630	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561637	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561640	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1056 10561641	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571128	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571310	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571330	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571334	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571335	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571346	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571349	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571351	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571354	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571359	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1057 10571361	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1066 10661128	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661328	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661334	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661347	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661349	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661350	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661351	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661352	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661353	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661354	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661356	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661357	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661359	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661361	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661362	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1066 10661365	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661367	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661368	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661369	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661373	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661374	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661375	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661376	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661377	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661378	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661380	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661381	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661382	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661383	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661384	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1066 10661385	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1066 10661387	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1068 10681004	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681005	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681008	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681009	Dose 1 all- available efficacy	Did not provide informed consent.
		Dose 2 all- available efficacy	Did not provide informed consent.
		Evaluable efficacy (7 Days)	Did not provide informed consent; had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681019	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681023	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681029	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681030	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681039	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1068 10681041	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681043	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681044	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681050	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681056	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681057	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681059	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681062	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681063	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681068	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681078	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681079	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1068 10681084	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1071 10711023	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1071 10711049	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711063	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711169	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711178	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711216	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711220	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711228	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711238	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711240	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711243	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711245	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1071 10711248	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1072 10721037	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1072 10721065	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771249	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771251	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771255	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771256	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771257	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771259	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771263	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771264	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771265	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771266	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1077 10771267	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771270	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1077 10771271	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791057	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791158	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791234	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791264	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791266	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791271	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791273	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791279	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791283	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791306	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791307	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791309	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791310	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791312	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1079 10791314	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1080 10801064	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1080 10801217	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1081 10811053	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1081 10811061	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1081 10811139	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1081 10811150	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821007	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821062	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821126	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1082 10821164	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821205	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821209	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821213	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821214	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821219	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1082 10821223	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831173	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831274	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831275	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831277	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831280	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1083 10831283	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841006	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841366	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1084 10841446	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841475	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841476	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841483	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841490	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841491	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841497	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1084 10841498	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841501	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841504	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841505	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841507	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841508	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841510	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841515	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841516	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841524	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841525	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841527	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841528	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841529	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1084 10841531	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1087 10871033	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871080	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871121	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871211	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871224	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871228	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871418	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871505	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871537	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871538	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871539	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871540	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871542	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871547	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871549	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871559	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1087 10871560	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871561	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871564	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871566	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871567	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871569	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871570	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871574	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871575	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871577	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871578	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871580	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871589	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871590	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1087 10871591	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1087 10871600	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1088 10881122	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1088 10881139	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1088 10881257	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1088 10881260	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1088 10881261	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1088 10881262	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1088 10881263	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1089 10891004	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1089 10891093	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1089 10891344	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901146	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901237	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901415	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901493	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901504	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901505	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901506	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901511	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901514	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901519	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901521	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901523	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901525	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901531	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1090 10901532	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901533	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901534	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901541	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901542	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901545	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901549	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901552	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901553	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901554	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901555	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901556	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901560	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901562	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901563	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1090 10901564	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901568	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1090 10901569	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911001	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1091 10911004	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1091 10911006	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911010	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1091 10911012	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1091 10911092	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911159	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1091 10911195	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911364	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911365	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911370	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911374	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1091 10911377	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921015	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921123	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921180	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1092 10921191	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921220	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921244	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921250	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921251	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921252	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921253	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921254	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921255	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921256	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921257	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921258	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921259	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921261	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921262	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1092 10921263	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921264	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921265	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921266	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921267	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921268	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921269	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1092 10921270	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921273	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921275	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921277	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1092 10921278	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931005	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931050	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931051	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1093 10931128	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931181	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931184	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931189	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931190	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931191	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931192	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931193	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931198	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931212	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1093 10931227	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941046	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941071	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941080	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941130	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941159	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941162	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941180	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941183	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941184	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941187	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1094 10941191	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951102	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1095 10951107	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1095 10951300	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961048	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961082	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961086	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961160	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961282	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1096 10961386	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1097 10971024	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1097 10971033	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1097 10971047	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1097 10971060	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1097 10971097	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1097 10971107	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1097 10971121	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1097 10971122	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1097 10971123	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1098 10981030	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1098 10981092	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1098 10981109	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1098 10981162	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1098 10981261	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1101 11011027	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1101 11011077	Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1101 11011109	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1101 11011112	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1101 11011116	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1101 11011119	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1101 11011120	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1107 11071093	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091101	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091248	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091313	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091345	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091374	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091407	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091475	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1109 11091503	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101241	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101309	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101351	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101353	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101355	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101357	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101358	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101359	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101362	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101363	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101364	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101366	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101367	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101368	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101369	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1110 11101373	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101376	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1110 11101378	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111106	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111193	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111194	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111195	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111196	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1111 11111197	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111198	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111199	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111201	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111202	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111204	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111206	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1111 11111207	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121052	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121118	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121134	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121255	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121302	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121309	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121312	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1112 11121314	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121316	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121321	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121325	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121327	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121329	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121330	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121334	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121337	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121338	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121340	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121344	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121347	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121348	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1112 11121349	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1112 11121350	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1116 11161117	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1116 11161118	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1116 11161227	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1116 11161253	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1117 11171040	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1117 11171047	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1117 11171052	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1117 11171155	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1117 11171193	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1117 11171194	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1117 11171195	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181065	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181072	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181113	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181114	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181118	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181119	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181120	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181123	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181124	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181125	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181126	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1118 11181127	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181128	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181129	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1118 11181130	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201066	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201073	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201127	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201213	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1120 11201227	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201316	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201317	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201327	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201330	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201333	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201335	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201336	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1120 11201338	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201341	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201345	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201347	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201349	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201350	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201351	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201353	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201355	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201358	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201359	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201360	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201361	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201362	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201368	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1120 11201369	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201372	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201374	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201375	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201377	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201378	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201379	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201380	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201382	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201383	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201384	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201387	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201389	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201390	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201394	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1120 11201397	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201399	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201400	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201403	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201408	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201410	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201411	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201412	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201413	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201414	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201415	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201419	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201421	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201422	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201423	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1120 11201424	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201426	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201428	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201432	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201434	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1120 11201435	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1121 11211071	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1122 11221034	Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1122 11221055	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1122 11221057	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1122 11221058	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1122 11221060	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231288	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231345	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231368	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231376	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231379	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231385	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231388	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231390	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231391	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231393	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231394	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1123 11231400	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231401	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231402	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1123 11231406	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1124 11241048	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251107	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251211	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251222	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251223	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251224	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251225	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251226	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251227	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251228	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251229	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251230	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1125 11251231	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251232	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251234	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1125 11251236	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1127 11271002	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1127 11271003	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1127 11271034	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1128 11281109	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1128 11281313	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1128 11281325	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291091	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1129 11291149	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291230	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291233	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291234	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291236	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291237	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291239	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1129 11291240	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291241	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291242	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291243	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291246	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291247	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291248	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291250	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291251	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1129 11291254	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301039	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1130 11301095	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301096	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1130 11301098	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311145	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311164	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1131 11311245	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311247	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311249	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311251	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311255	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311256	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311258	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311259	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1131 11311262	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331197	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331426	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331469	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331472	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1133 11331481	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341052	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1134 11341067	Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria.
	C4591001 1134 11341087	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341099	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341101	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341130	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341339	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341353	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341388	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341403	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341409	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341414	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341415	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341418	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341419	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341422	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341423	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341429	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1134 11341430	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341431	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341432	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341434	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1134 11341439	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351128	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1135 11351131	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361070	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361074	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361075	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361077	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361078	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361079	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361080	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361081	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361085	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1136 11361088	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361089	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361093	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361097	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361102	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361103	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361104	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1136 11361105	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391111	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391115	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391118	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391121	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391122	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391124	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391126	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1139 11391128	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1139 11391129	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401035	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401082	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401292	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401293	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401297	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401300	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1140 11401302	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401305	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401307	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401312	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1140 11401313	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411066	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1141 11411196	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411258	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411259	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1141 11411268	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421111	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421266	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421272	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421288	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421294	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421296	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1142 11421297	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421301	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421302	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421304	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421305	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421309	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1142 11421312	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1145 11451076	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1145 11451109	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1145 11451111	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1145 11451113	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1145 11451114	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1147 11471004	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491117	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491126	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1149 11491224	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491239	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491278	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491296	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491298	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491325	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491330	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491333	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491338	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491341	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1149 11491343	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521359	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521476	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521497	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521513	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1152 11521516	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521518	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521524	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521525	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521526	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521527	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521528	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521530	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521531	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521532	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521536	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521538	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521539	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521540	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521542	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1152 11521543	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521544	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521545	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521546	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521547	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521548	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521550	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521553	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521554	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521555	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521556	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521558	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521559	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521561	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521562	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1152 11521563	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521564	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521565	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521567	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521572	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521573	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521574	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521576	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521578	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521579	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521580	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521581	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521582	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521585	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1152 11521586	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1156 11561044	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561092	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561228	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561237	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561238	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561240	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561241	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561242	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1156 11561261	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561266	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561267	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561269	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561271	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561278	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561279	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561280	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561284	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1156 11561285	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571028	Dose 1 all-available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571131	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571144	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571157	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571158	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571159	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571160	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571161	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571162	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571163	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571164	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571165	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1157 11571167	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571171	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571172	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571173	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571175	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571177	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1157 11571178	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1161 11611003	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611012	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611013	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611021	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611022	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611025	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611029	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1161 11611030	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611031	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611035	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611036	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611037	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611038	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611042	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1161 11611043	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1161 11611044	Dose 2 all-available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1162 11621006	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621007	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621212	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621213	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621278	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621297	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621327	Dose 2 all-available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621349	Dose 2 all-available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621407	Dose 2 all-available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1162 11621433	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621497	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621498	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621501	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621507	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621508	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621509	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621512	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621516	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621521	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621528	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621531	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621536	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621542	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621544	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1162 11621546	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621547	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621550	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621552	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621555	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621556	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621557	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621558	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621560	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621561	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621562	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621564	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621565	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621567	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621568	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1162 11621575	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621578	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1162 11621581	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1163 11631003	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631005	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631007	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631008	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631010	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631011	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1163 11631013	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631100	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1163 11631126	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631131	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631132	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631133	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631144	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1163 11631149	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1166 11661098	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1166 11661100	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1166 11661102	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1166 11661105	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1166 11661107	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1166 11661108	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1166 11661111	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1167 11671122	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1167 11671123	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1168 11681015	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1168 11681230	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1168 11681232	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1168 11681233	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1168 11681235	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1168 11681236	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1168 11681237	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1168 11681240	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1169 11691070	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701067	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701160	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701354	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701409	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701448	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1170 11701454	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711160	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711215	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711217	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711218	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711220	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711222	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711227	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1171 11711230	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711232	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711233	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711235	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711243	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1171 11711244	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771089	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1177 11771232	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771476	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771508	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771518	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1177 11771519	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771522	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771523	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771527	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771530	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771535	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771536	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771538	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771542	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771545	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771546	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771547	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771553	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771558	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771559	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1177 11771560	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1177 11771561	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1178 11781056	Dose 1 all- available efficacy	Did not receive at least 1 vaccination.
		Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1178 11781299	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1178 11781306	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1178 11781307	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1178 11781308	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1178 11781313	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1178 11781315	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791124	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791127	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791128	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791129	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791132	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791134	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791135	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791140	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791141	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791142	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1179 11791151	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851001	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851003	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1185 11851004	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851006	Dose 1 all-available efficacy Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not receive at least 1 vaccination. Did not complete 2 vaccination doses. Randomized but did not meet all eligibility criteria; did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851007	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851014	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851016	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851019	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851020	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1185 11851027	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851031	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851034	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851035	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851037	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851042	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851044	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851045	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851046	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851047	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851057	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851058	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851061	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851062	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1185 11851065	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1194 11941001	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941002	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941005	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941006	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941007	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941008	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941013	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941015	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941018	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941021	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941022	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941027	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941028	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941029	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941035	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1194 11941036	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941037	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941038	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941039	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941040	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941042	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941049	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941050	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941055	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941059	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941060	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941063	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941064	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941065	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941068	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1194 11941073	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941074	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941075	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941076	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941077	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941078	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941079	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941084	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941085	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941094	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941095	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941099	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941101	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1194 11941102	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951007	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1195 11951011	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951014	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951028	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951031	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951037	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951038	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951039	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951045	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951046	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951049	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951050	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951052	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951057	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951058	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951059	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1195 11951069	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951078	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951086	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951087	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951088	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951094	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951095	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951096	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951097	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951102	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951103	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951110	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951111	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951112	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951121	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1195 11951122	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951124	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951125	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951126	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951127	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951128	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951129	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951130	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951131	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951132	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951133	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951143	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951144	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951145	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951149	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1195 11951150	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951151	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951152	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1195 11951156	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971008	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971009	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971011	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971012	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971013	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971016	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971021	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971027	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971033	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971034	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971036	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971037	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1197 11971038	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971043	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971044	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971046	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971047	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971048	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971049	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971050	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971051	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1197 11971052	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971054	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971055	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971056	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971057	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971061	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971062	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971063	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1197 11971065	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971066	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971067	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971070	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971071	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971072	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971073	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971074	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971075	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971076	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971080	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971081	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971082	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971083	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971084	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1197 11971085	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971086	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971087	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971089	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971090	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971091	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971095	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971097	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971098	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971099	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971100	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1197 11971101	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1202 12021001	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1202 12021002	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1202 12021003	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1202 12021004	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1202 12021005	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1202 12021006	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1202 12021008	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1202 12021012	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031002	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031003	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031006	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031007	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031009	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031011	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031012	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031013	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031014	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031016	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1203 12031017	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031018	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031022	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031024	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031025	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031027	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031028	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031029	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031038	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031039	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031040	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031043	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031050	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031054	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031055	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1203 12031061	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1203 12031068	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041057	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041231	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041249	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041250	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041251	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041254	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041266	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041282	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041289	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1204 12041291	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1205 12051001	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1205 12051002	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1205 12051005	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 120512051006	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051007	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051008	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051009	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051016	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051018	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051019	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051020	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051031	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051037	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051038	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051039	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051040	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051045	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120512051046	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1207 12071001	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071004	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071015	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071017	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071019	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071020	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071022	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071029	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071030	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071031	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071034	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071035	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1207 12071043	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081006	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1208 12081014	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 120812081015	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120912091005	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120912091012	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 120912091014	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 121012101003	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 121012101004	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 121012101042	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 121012101043	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1210 12101044	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1212 12121021	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131007	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131009	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131011	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131017	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131020	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1213 12131021	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131022	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131023	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131024	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131027	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131029	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131030	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1213 12131031	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141002	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141003	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141006	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141010	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141011	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141021	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1214 12141026	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1214 12141028	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171001	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171004	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171006	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171007	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171024	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171025	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171026	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171027	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171029	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171033	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171036	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1217 12171043	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1218 12181002	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1219 12191020	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1219 12191021	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1219 12191025	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1219 12191027	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1219 12191031	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201006	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1220 12201034	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1221 12211009	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1221 12211015	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1221 12211016	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1221 12211017	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1221 12211018	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1221 12211021	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231248	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231254	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231255	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1223 12231257	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231259	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231261	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231262	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231263	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1223 12231266	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1224 12241012	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1224 12241057	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1226 12261613	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262177	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262222	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262235	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262240	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262248	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262250	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262253	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262254	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262257	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262264	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262265	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262266	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262271	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262277	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1226 12262281	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262288	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262296	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262302	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262305	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262306	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262308	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262310	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262312	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262323	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262324	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262325	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262328	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262332	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262333	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1226 12262336	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262342	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262344	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262345	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262349	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262355	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1226 12262358	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1229 12291041	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1229 12291080	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1229 12291210	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12311057	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12311549	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311672	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311709	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311723	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311815	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311935	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12311979	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312098	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312130	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312347	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312496	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12312571	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313003	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313039	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313090	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1231 12313103	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313359	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313391	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313446	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313457	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12313461	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313468	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313478	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313480	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313496	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313503	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313511	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313524	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313530	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313536	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313538	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313549	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12313562	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1231 12313651	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314060	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314120	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314189	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314216	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314301	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314488	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12314863	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1231 12314972	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12315018	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12315246	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12315608	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1231 12315625	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1231 12315672	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321105	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321127	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321144	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1232 12321234	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321242	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321281	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321284	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321325	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321326	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321334	Dose 2 all- available efficacy  Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses.  Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321342	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321349	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321357	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321360	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321363	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321365	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321367	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321368	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1232 12321369	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321372	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321375	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321379	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321381	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321383	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321387	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321388	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321389	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321390	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321392	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321398	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321399	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321403	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321405	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1232 12321407	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321409	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321410	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321411	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1232 12321418	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351179	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351182	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351194	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351198	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351199	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351201	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351202	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351203	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351204	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351205	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1235 12351206	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351210	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351211	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351213	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351216	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351220	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351221	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1235 12351227	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412191	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412196	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412200	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412205	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412219	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412220	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412224	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412230	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412231	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412238	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412241	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412242	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412250	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412251	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412263	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412266	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412272	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412273	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412286	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412287	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412297	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412298	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412300	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412302	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412305	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412309	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412310	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412316	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412318	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412319	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412325	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412326	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412340	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412349	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412356	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412359	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412372	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412376	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412384	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412408	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412446	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412469	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412474	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412483	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412484	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412487	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412488	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412489	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412492	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412496	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412497	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412499	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412503	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412511	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412514	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412520	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412521	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412522	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412524	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412526	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412533	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412536	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412538	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412541	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412542	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412545	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412555	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1241 12412567	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1241 12412568	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1247 12471066	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1247 12471135	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1247 12471166	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1248 12481026	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1248 12481044	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1248 12481047	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1248 12481049	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1248 12481214	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511047	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511050	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1251 12511067	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511078	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511087	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511236	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511243	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511244	Dose 2 all- available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1251 12511248	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511249	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511250	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511251	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511257	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511258	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511260	Dose 2 all-available efficacy Evaluable efficacy (7 Days)	Did not complete 2 vaccination doses. Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511261	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511263	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511264	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511265	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1251 12511267	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1252 12521003	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541002	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541004	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541010	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541011	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541014	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.



**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1254 12541016	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541018	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541019	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541025	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541026	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541037	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1254 12541191	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541192	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541195	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541196	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541197	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541198	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541200	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541203	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541207	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1254 12541209	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1258 12581068	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1258 12581076	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1260 12601003	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1260 12601008	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1260 12601025	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1260 12601026	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1260 12601027	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1260 12601030	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1260 12601033	Evaluable efficacy (7 Days)	Had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1260 12601095	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1260 12601121	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641195	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641214	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641217	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641219	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641220	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641222	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641223	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641224	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641229	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 1264 12641230	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 1265 12651026	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1); had other important protocol deviations on or prior to 7 days after Dose 2.
	C4591001 1270 12701057	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441152	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441495	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44441792	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442012	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442061	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442074	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442075	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

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**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 4444 44442076	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442078	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442092	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442096	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442098	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442108	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442110	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442112	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442116	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442126	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442127	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442130	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442132	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442134	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442139	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Population</b>	<b>Reason for Exclusion</b>
	C4591001 4444 44442141	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442150	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442164	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442166	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442169	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442176	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442179	Dose 2 all-available efficacy	Did not complete 2 vaccination doses.
		Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442183	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442187	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442204	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442208	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442239	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442243	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442266	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

**16.2.3.1.IA1 Listing of Subjects Excluded From All-Available and Evaluable Efficacy Population – Interim Analysis 1**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 4444 44442271	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442282	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442290	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442295	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442296	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442309	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).
	C4591001 4444 44442316	Evaluable efficacy (7 Days)	Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1).

Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.

PFIZER CONFIDENTIAL SDTM Creation: 06NOV2020 (01:29) Source Data: adsl Table Generation: 01DEC2020 (01:46)

(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File: ./nda2\_unblinded\_ia/C4591001\_IA\_62\_Renumbered/adsl\_1001\_excl\_eff\_pop