

16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
16-55	C4591001 1001 10011125	1	37	09SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Withdrew consent and decided not to continue in study.
		1	37	09SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient withdrew consent
	C4591001 1003 10031140			04AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Randomized in error.
	C4591001 1003 10031143			04AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Randomized in error.
	C4591001 1005 10051238	2	65	06JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WAS UNBLINDED AND FOUND OUT HE RECEIVED PLACEBO. HE DECIDED TO WITHDRAW
	C4591001 1005 10051308	1	1	19OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	busy work schedule
		1	1	19OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	busy work schedule
	C4591001 1005 10051341	1	2	22OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject tested COVID positive between visits 1 and 2
	C4591001 1005 10051381			28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject decided to withdraw consent after randomized in IVRS but before given vaccine
	C4591001 1005 10051407	2	16	18DEC2020	VACCINATION	OTHER	subject proceeded to open label prior to V3 in the blinded Rx phase
	C4591001 1006 10061078	2	128	15JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Non-study COVID-19 Vaccine

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	C4591001 1006 10061109	2	148	08FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Received non-study covid-19 vaccine
	C4591001 1006 10061148	2	93	31DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrew consent to participate in a different research study
	C4591001 1006 10061161	2	91	15JAN2021	REPEAT SCREENING 1	NO LONGER MEETS ELIGIBILITY CRITERIA	Participant is pregnant
	C4591001 1006 10061174	2	113	22FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Inclusion 2
	C4591001 1007 10071108	2	29	24SEP2020	VACCINATION	PROTOCOL DEVIATION	Missed visit 3
	C4591001 1007 10071110	2	155	25JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071179	2	29	01OCT2020	VACCINATION	PROTOCOL DEVIATION	unable to contact subject
	C4591001 1007 10071186	2	182	03MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071212	2	117	02JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071218	2	120	06JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end

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	C4591001 1007 10071225	2	134	19JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071243	2	120	06JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071250	2	174	08MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071266	2	106	30DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071269	2	114	07JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071276	2	105	30DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071286	2	112	06JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071295	2	155	17FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071339	2	100	10FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071380	2	58	06JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end

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	C4591001 1007 10071387	2	58	07JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071407	1	15	05NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion # 5; Subject has diagnosis of COVID-19 with positive PCR and symptoms
	C4591001 1007 10071556	2	29	26JAN2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion #12; received COVID vaccine outside of study
		2	29	26JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1008 10081480	2	115	04FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	site unable to make contact with subject despite numerous attempts
	C4591001 1008 10081698	2	69	25JAN2021	VACCINATION	LOST TO FOLLOW-UP	subject missed V3, no return calls/contact to date despite numerous attempts per site
		2	69	25JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	subject missed V3, no return calls/contact to date despite numerous attempts per site
	C4591001 1008 10081721	1	13	10NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject tested positive for COVID 19
	C4591001 1009 10091133	2	111	06JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Previously received COVID-19 vaccination on 1/5/2021
	C4591001 1009 10091185	2	137	22FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Vaccinated outside research study with COVID-19 Vaccine
	C4591001 1009 10091211	1	19	03NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject tested positive for COVID-19

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	C4591001 1009 10091235	2	107	25FEB2021	REPEAT SCREENING 1	OTHER	Visit 101 delayed due to recent vaccination
	C4591001 1009 10091257	1	10	05NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	positive for COVID-19
	C4591001 1009 10091286	2	13	04JAN2021	VACCINATION	OTHER	subject transitioned to open prior to visit 3
	C4591001 1011 10111092	2	142	04FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdrew COntent
	C4591001 1012 10121078	2	66	19NOV2020	VACCINATION	LOST TO FOLLOW-UP	Call attempts: 10/20/2020, 10/28/2020 and 10/30/2020 No response to cert letter delivered 11/12/2020
		2	66	19NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Call attempts: 10/20/2020, 10/28/2020 and 10/30/2020 No response to cert letter delivered 11/12/2020
	C4591001 1012 10121096	2	65	24NOV2020	VACCINATION	LOST TO FOLLOW-UP	19OCT2020, 27OCT2020 failed attempts to reach. Cert letter sent 28OCT2020 returned to site.
		2	65	24NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	19OCT2020, 27OCT2020 failed attempts to reach. Cert letter sent 28OCT2020 returned to site.
	C4591001 1012 10121103	2	2	23SEP2020	VACCINATION	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT/PRODUCT ADMINISTRATION ERROR
		2	2	23SEP2020	FOLLOW-UP	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT/PRODUCT ADMINISTRATION ERROR

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	C4591001 1012 10121119	2	154	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Multiple phone calls and certified letter sent; no response from subject. Considered LTFU.
	C4591001 1012 10121138	2	137	08FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrawn.
	C4591001 1012 10121163	1	16	24SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/INJECTION SITE DERMATITIS
		1	39	17OCT2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/INJECTION SITE DERMATITIS
	C4591001 1012 10121166	2	100	07JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Attempts to reach 23NOV2020, 24NOV2020 and 25NOV2020. Certified letter sent 30Nov2020
	C4591001 1013 10131017			30JUL2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT FROM STUDY.
	C4591001 1013 10131046	2	70	27OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject is lost to follow up. certified letter sent and emailed 10-02-2020
		2	70	27OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT IS LOST TO FOLLOW UP.
	C4591001 1013 10131048	2	28	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	New job
		2	28	17SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	New Job
	C4591001 1013 10131054	2	7	30AUG2020	VACCINATION	LOST TO FOLLOW-UP	Attempted contact
		2	7	30AUG2020	FOLLOW-UP	LOST TO FOLLOW-UP	Contact attempted

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	C4591001 1013 10131116	2	191	11MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT DISTANCE AND AVAILABILITY
	C4591001 1013 10131131	2	36	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	Certified letter sent
		2	36	07OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent
	C4591001 1013 10131138	1	23	02SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT FROM THE STUDY
		1	23	02SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT.
	C4591001 1013 10131216	1	46	02OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew from study
		1	46	02OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT DUE TO FAMILY SITUATION.
	C4591001 1013 10131332	2	56	09NOV2020	VACCINATION	LOST TO FOLLOW-UP	UNKOWN
		2	56	09NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	UNKNOWN
	C4591001 1013 10131395	2	45	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	ATTEMPTED TO CONTACT.
		2	45	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	UNABLE TO CONTACT SUBJECT AFTER MULTIPLE ATTEMPTS.
	C4591001 1013 10131426	1	1	03SEP2020	VACCINATION	LOST TO FOLLOW-UP	subject has not returned for next visit. is now considered lost to follow up

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	C4591001 1013 10131550	2	47	20NOV2020	VACCINATION	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT.
		2	47	20NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT WITHOUT RESPONSE.
	C4591001 1013 10131552	2	39	12NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	UNABLE TO CONTACT SUBJECT. CERTIFIED LETTER SENT WITHOUT RESPONSE.
		2	131	12FEB2021	VACCINATION	LOST TO FOLLOW-UP	MULTIPLE ATTEMPTS TO CONTACT.
	C4591001 1013 10131573	2	1	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT HAS ONLY COMPLETED VISIT 2. IS NOW CONSIDERED A LOST TO FOLLOW UP.
		2	45	20NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT IS LOST TO FOLLOW. HAS NOT RESPONDED TO CERTIFIED LETTER.
	C4591001 1013 10131592	2	31	11NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent from study.
		2	31	11NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	MOVED OUT OF STATE NO LONGER WANTED TO PARTICIPATE.
	C4591001 1013 10131605	2	1	15OCT2020	VACCINATION	OTHER	SUBJECT DID NOT COMPLETE V3POST VISIT. SUBJECT ENTERED V101VAX3.
	C4591001 1013 10131670†	1	4	11OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	SUBJECT TESTED POSITIVE FOR COVID-19
	C4591001 1013 10131683	2	129	10MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT DID NOT WISH TO CONTINUE IN STUDY.
	C4591001 1013 10131701	2	29	01DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT STATED THAT HE NO LONGER WANTS TO BE A PART OF STUDY.

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		2	29	01DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT FROM THE STUDY.
	C4591001 1013 10131740			15OCT2020	FOLLOW-UP	OTHER	randomized in error, needed to wait until course of antibiotics was done.
	C4591001 1013 10131746	1	22	09NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Currently taking corticosteroids
		1	22	09NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW FROM THE STUDY.
	C4591001 1013 10131756	2	84	03FEB2021	VACCINATION	WITHDRAWAL BY SUBJECT	Subject no longer wanted to travel to the visits.
		2	84	03FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wanted to travel to visits.
	C4591001 1013 10131791	2	120	10MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT NO LONGER WANTED TO PARTICIPATE IN STUDY.
	C4591001 1015 10151030	2	64	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject lost to follow up after multiple contact attempts and receipt of certified letter
		2	64	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject lost to follow up after multiple contact attempts and receipt of certified letter
	C4591001 1015 10151199	1	24	01OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject decided not to continue with study.
		1	24	01OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
	C4591001 1016 10161087	1	22	31AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/INJECTION SITE SWELLING

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	C4591001 1016 10161126	1	39	21SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject declined further study vaccines,subject will continue with rest of visits and procedures
		1	194	23FEB2021	FOLLOW-UP	OTHER	non-compliance with study
	C4591001 1016 10161280	2	112	21JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received covid vaccine outside of the study
	C4591001 1016 10161348	1	10	14NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject had positive pcr covid test
	C4591001 1018 10181009	2	129	28DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	reported received vaccine at work.
	C4591001 1018 10181025	1	45	16SEP2020	VACCINATION	LOST TO FOLLOW-UP	Follow-up attempts made on 21-Aug, 1-Sep, and 4-Sep with no response.
		1	45	16SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Follow-up attempts made on 21-Aug, 1-Sep, and 4-Sep. Certified letter sent 9-Sep-2020.
	C4591001 1018 10181027	2	156	26JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received non study covid vaccine
	C4591001 1018 10181036	1	45	16SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject missed V2 and did not respond to 3 Follow-up attempts.
		1	45	16SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	no response to multiple follow up calls and contact attempts
	C4591001 1018 10181039	2	150	18JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received non study covid vaccine

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	C4591001 1018 10181054	1	39	11SEP2020	VACCINATION	LOST TO FOLLOW-UP	patient returned to home country, did not respond to outreach, certified letter sent
		1	39	11SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject returned to home country, according to call to emergency contact
	C4591001 1018 10181058	2	114	16DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	(b) (6) , received vaccine through her workplace.
	C4591001 1018 10181105	2	115	18DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	The subject had the vaccination at work prior to being unblinded.
	C4591001 1018 10181113	2	108	16DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Will get vaccine from work
	C4591001 1018 10181127	2	96	16DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Will get vaccine from work.
	C4591001 1018 10181141	2	106	16DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	scheduled to get vaccine at work.
	C4591001 1018 10181142	1	33	14SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject did not arrive at scheduled second visit and texted no longer wants to participate in study.
		1	33	14SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject did not arrive at scheduled second visit and texted no longer wants to participate in study.
	C4591001 1018 10181151	2	174	23FEB2021	OPEN LABEL TREATMENT	WITHDRAWAL BY SUBJECT	Subject does not want to continue in study.
		2	174	23FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject stated she does not want to continue in the study.

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	C4591001 1018 10181164	2	111	23DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject will get vaccine at work.
	C4591001 1018 10181170	2	97	16DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient wants to be vaccinated at her place of work
	C4591001 1018 10181191	2	110	28DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Wanting to get out of study vaccination
	C4591001 1018 10181204	2	102	21DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Received vaccine at work place.
	C4591001 1018 10181214	2	98	21DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	she received Pfizer Covid 19 Vaccine at her workplace on 18DEC2020
	C4591001 1018 10181223	2	83	16DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	informed us he received vaccine at his workplace (b) (6) on 16-Dec-2020.
	C4591001 1018 10181266	1	41	14OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdraw from study due to work schedule
		1	41	14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdraw from study due to work schedule
	C4591001 1018 10181302	2	69	16DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Wanting to get out of study vaccination
	C4591001 1018 10181306	2	95	14JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received vaccine prior to being unblinded

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	C4591001 1018 10181310	1	57	07DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject is unable to be on site for the following visits due to personal reasons.
		1	57	07DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject is unable to be on site for the following visits due to personal reasons.
	C4591001 1018 10181311	1	57	07DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	unable to return to site for the following visits due to personal reasons.
		1	57	07DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject is unable to return to site for the following visits due to personal reasons.
	C4591001 1018 10181313	1	57	07DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject was no longer able to comply with study
		1	57	07DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Was no longer able to comply with study procedures.
	C4591001 1018 10181319	2	44	16DEC2020	REPEAT SCREENING 1	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject received COVID vaccine from workplace Saturday, 19-DEC-2020
		2	49	21DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received COVID vaccine from workplace Saturday, 19-DEC-2020
	C4591001 1018 10181335	2	104	24FEB2021	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
		2	104	24FEB2021	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1019 10191063	2	126	12JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject had Moderna vaccine elsewhere.
	C4591001 1019 10191098	1	18	11SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Pt discontinued due to positive covid test. Will f/u with pt

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		1	175	15FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Unable to contact subject
	C4591001 1019 10191166	1	22	25SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
		1	22	25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
	C4591001 1019 10191192	2	49	18NOV2020	VACCINATION	LOST TO FOLLOW-UP	lost to follow up
		2	49	18NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1021 10211127	2	88	19DEC2020	FOLLOW-UP	DEATH	DEATH/CARDIAC FAILURE CONGESTIVE
	C4591001 1021 10211223	2	82	28DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject requested to withdraw from study and be unblinded.
	C4591001 1024 10241026	2	129	15JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient withdrew consent
	C4591001 1024 10241036	2	127	14JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew their consent
	C4591001 1027 10271105	1	15	11SEP2020	VACCINATION	ADVERSE EVENT	Subject has discontinued Study Drug. Subject has agreed to continue with follow-up visits./DRUG HYPERSENSITIVITY
	C4591001 1028 10281003	2	109	21DEC2020	FOLLOW-UP	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY
	C4591001 1028 10281072	1	55	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	certified letter returned unclaimed 20oct2020

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Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1028 10281216	1	55	20OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter came back unclaimed on 20Oct2020 multiple attempts made, certified letter signed for, but no contact from patient. Lost to follow up
		2	66	18DEC2020	VACCINATION	LOST TO FOLLOW-UP	
	C4591001 1028 10281285	2	66	18DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	attempted multiple times to contact, certified letter sent. Patient lost to follow up
		1	22	17NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Patient tested positive between visit 1 and visit 2
	C4591001 1028 10281294	1	7	04NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	patient had positive covid test prior to V2
	C4591001 1036 10361011	1	1	20AUG2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1036 10361032	1	1	20AUG2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
		2	48	03NOV2020	VACCINATION	LOST TO FOLLOW-UP	unreachable
	C4591001 1036 10361050	2	48	03NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	unreachable
					31AUG2020	FOLLOW-UP	OTHER
	C4591001 1036 10361061	2	155	22FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow-up
	C4591001 1036 10361062	2	136	03FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject didn't return for Convalescent visit & multiple attempts to contact have been unsuccessful

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1036 10361073	2	151	22FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow-up
	C4591001 1036 10361096	2	43	16NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject is incarcerated.
		2	43	16NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is incarcerated
	C4591001 1036 10361100	2	143	22FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow-up
	C4591001 1036 10361118	2	113	22FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow-up
	C4591001 1036 10361127	1	61	15DEC2020	VACCINATION	LOST TO FOLLOW-UP	Subject didn't return for V2VX2L and didn't respond to registered letter.
		1	61	15DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject didn't return for V2VX2L and didn't respond to registered letter.
	C4591001 1036 10361128	1	61	15DEC2020	VACCINATION	LOST TO FOLLOW-UP	Subject didn't return for V2VX2L and didn't respond to registered letter.
		1	61	15DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject didn't return for V2VX2L and didn't respond to registered level.
	C4591001 1037 10371037	2	134	26JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT TO PARTICIPATE
	C4591001 1037 10371050	2	173	05MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT RECIEVED VAX IN COMMUNITY

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1037 10371077	1	66	30OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	SPOKE WITH SUBJECT ON 30 OCT. DUE TO SCHEDULE, HE CAN NO LONGER CONTINUE WITH STUDY VISITS
		1	66	30OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SPOKE WITH SUBJECT ON 30 OCT. DUE TO SCHEDULE, HE CAN NO LONGER ATTEND VISITS
	C4591001 1037 10371078	1	44	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	SITE ATTEMPTED CONTACT ON 22 SEP 30 SEP AND CERTIFIED LETTER SENT 8 OCT NO RESPONSE
		1	44	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT 8 OCT. PT DID NOT RESPOND
	C4591001 1037 10371219	2	75	18DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	PT GOT VACCINE IN COMMUNITY. DOES NOT WISH TO CONTINUE IN TRIAL.
	C4591001 1037 10371330	2	120	23FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJ WITHDREW CONSENT TO PARTICIPATE. PT DOES NOT WANT VACCINE
	C4591001 1039 10391021	1	24	17SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Patient tested positive for COVID-19.
		1	120	22DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient was able to receive vaccine outside of study and withdrew to get vaccine
	C4591001 1039 10391080	1	21	23SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Patient withdrew consent. Patient will not be participating in follow-ups.
		1	21	23SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient withdrew from study and follow up.
	C4591001 1039 10391093	2	137	08FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Contacted multiple times via phone and email, and was sent certified letter, all with no response

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1039 10391124	2	97	05JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Patient received COVID vaccine outside of study
	C4591001 1039 10391186	2	62	28DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient had to leave before vaccination and decided to discontinue.
	C4591001 1039 10391196	2	69	12JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient withdrew and reports she will be receiving the vaccine outside of the study.
	C4591001 1039 10391244	1	13	23NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Patient tested positive for COVID-19.
	C4591001 1042 10421008	2	110	08DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Personal Decision
	C4591001 1042 10421028	2	161	02FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received vaccination outside of study
	C4591001 1042 10421069	1	22	31AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
		1	22	31AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1042 10421092	2	27	06OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject called the office in withdrew consent-they will not be returning to the site for future visi
		2	27	06OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew from study participation
	C4591001 1042 10421093	2	94	04DEC2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up after unsuccessful attempts to make contact.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		2	94	04DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up after unsuccessful attempts to make contact.
	C4591001 1042 10421106	2	120	30DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdrew Consent
	C4591001 1042 10421112	2	111	28DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrew consent
	C4591001 1042 10421129	2	41	19OCT2020	VACCINATION	OTHER	subject was LTFU but re-joined the trial for open label phase
	C4591001 1042 10421250	1	58	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up
		1	58	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1042 10421251	1	58	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1042 10421262	2	52	23DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Received Vaccine outside of study
	C4591001 1044 10441151	2	67	21DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	discontinued
	C4591001 1044 10441287	1	19	29DEC2020	VACCINATION	OTHER	subject proceeded to open label prior to Vax2 in the blinded treatment phase.
	C4591001 1046 10461040	1	15	31AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject chose to discontinue due to personal reasons.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	15	31AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Decision
	C4591001 1046 10461049	2	31	09OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject Withdrew
		2	31	09OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject decision
	C4591001 1046 10461099	1	64	27OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject Decision
		1	64	27OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Decision
	C4591001 1046 10461140	1	22	19SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject Decision
		1	22	19SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Decision
	C4591001 1046 10461290	2	119	25FEB2021	VACCINATION	WITHDRAWAL BY SUBJECT	Subject Moved out of State
		2	119	25FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew due to moving.
	C4591001 1047 10471112	2	1	06OCT2020	VACCINATION	OTHER	Waiting for certified letter return to change staus to lost to follow up
	C4591001 1047 10471126	2	103	05JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrew consent
	C4591001 1047 10471166	2	134	10FEB2021	VACCINATION	LOST TO FOLLOW-UP	lost to follow up

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		2	134	10FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up
	C4591001 1047 10471221	1	44	29OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrew consent
		1	44	29OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew consent
	C4591001 1047 10471234	2	127	11FEB2021	VACCINATION	LOST TO FOLLOW-UP	subject is lost to follow up
		2	127	11FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up
	C4591001 1047 10471314	1	36	16NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject is lost to follow up
		1	36	16NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up
	C4591001 1048 10481027	2	154	16FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	protocol deviation non study covid 19 vaccine
	C4591001 1048 10481070	2	144	11FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	pt was vaccinated outside of the study.
	C4591001 1048 10481085	2	87	20DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	subject received non study vaccination under EUA
	C4591001 1048 10481088	2	49	12NOV2020	VACCINATION	OTHER	out of state at time of visit 3
	C4591001 1052 10521022	2	63	11NOV2020	VACCINATION	LOST TO FOLLOW-UP	lost to follow up
		2	63	11NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1052 10521054	1	25	21SEP2020	VACCINATION	LOST TO FOLLOW-UP	n/a
		1	25	21SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up
	C4591001 1052 10521057	1	25	21SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrew consent
		1	25	21SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrawal by subject
	C4591001 1052 10521058	1	25	21SEP2020	VACCINATION	LOST TO FOLLOW-UP	lost to follow up
		1	25	21SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up
	C4591001 1052 10521064	1	25	24SEP2020	VACCINATION	LOST TO FOLLOW-UP	n/a
		1	25	24SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost of follow up
	C4591001 1052 10521080	1	28	29SEP2020	VACCINATION	LOST TO FOLLOW-UP	lost of follow up
		1	28	29SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost of follow up
	C4591001 1052 10521121	2	93	06JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECEIVED covid-19 VACCINE OUT OF STUDY PROTOCOL
	C4591001 1052 10521139	1	34	22OCT2020	VACCINATION	LOST TO FOLLOW-UP	lost to follow-up
		1	34	22OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow-up

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1052 10521155	2	136	24FEB2021	OPEN LABEL TREATMENT	WITHDRAWAL BY SUBJECT	withdrawal by subject
		2	136	24FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal by subject
	C4591001 1054 10541007	2	130	15JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	unblinding of subject occurred due to future non-study covid-19 vaccination
	C4591001 1054 10541022	1	64	23OCT2020	VACCINATION	LOST TO FOLLOW-UP	Pt deemed LTFU by site.
		1	64	23OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Pt deemed LTFU by site.
	C4591001 1054 10541023	1	64	23OCT2020	VACCINATION	LOST TO FOLLOW-UP	Pt deemed LTFU by site.
		1	64	23OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Pt deemed LTFU by site.
	C4591001 1054 10541033	1	21	11SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Per sponsor, participant met EXC #5, and should not receive VAX2 but may remain in study.
	C4591001 1054 10541055	1	59	23OCT2020	VACCINATION	LOST TO FOLLOW-UP	Pt deemed LTFU by site.
		1	59	23OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Pt deemed LTFU by site.
	C4591001 1054 10541064	1	78	12NOV2020	VACCINATION	LOST TO FOLLOW-UP	> 3 attempts at contacting pt via telephone; certified letter sent
		1	78	12NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	> 3 attempts at contacting pt via telephone; certified letter sent

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1054 10541076	2	152	19FEB2021	VACCINATION	LOST TO FOLLOW-UP	More than 3 phone contacts attempted & certified letter was sent.
		2	152	19FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	More than 3 phone contacts attempted & certified letter was sent.
	C4591001 1054 10541088	2	123	22JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	unblinding of subject occurred due to future non-study covid-19 vaccination
	C4591001 1054 10541110	2	96	29DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	EXC 12 met: previous vaccination with any coronavirus vaccine.
		2	96	29DEC2020	REPEAT SCREENING 1	NO LONGER MEETS ELIGIBILITY CRITERIA	Pt. received non-study vaccination on 18Dec20.
	C4591001 1054 10541138	1	23	02OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject doesn't want to continue in study.
		1	23	02OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject doesn't want to continue in study.
	C4591001 1054 10541150	1	22	05OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	No longer interested in study, and walked out of clinic w/o talking to Investigator.
		1	22	05OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt is no longer interested in study. Walked out of clinic w/o seeing the Investigator.
	C4591001 1054 10541154	2	90	13JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Unblinding of subject occurred due to future non-study COVID-19 vaccination.
	C4591001 1054 10541161	2	101	15JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received non-study covid-19 vaccination on 24Dec20.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1054 10541165	2	47	24NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subj. did not show up for V3, despite sending certified letter and contacting pt via phone 3 times.
		2	47	24NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subj. did not show up for V3, despite sending certified letter and contacting pt via phone 3 times.
	C4591001 1054 10541190	2	90	01FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt withdrew consent.
	C4591001 1054 10541201	2	112	11MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt withdrew consent on 11Mar21 over the phone.
	C4591001 1055 10551152	2	107	05JAN2021	OPEN LABEL TREATMENT	PROTOCOL DEVIATION	Subject received the second dose of vaccine (vax 4) outside of the study.
		2	107	05JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew from study to received COVID vaccine outside of study
	C4591001 1055 10551176	2	87	18DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew from study prior to Subject receiving Covid-19 vaccine outside of study
	C4591001 1056 10561027	1	35	25SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject couldn't be reached. Caregiver states he left the house and nobody knows where he is.
		1	35	25SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject couldn't be reached. Caregiver states he left the house and nobody knows where he is.
	C4591001 1056 10561129	1	24	25SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject states he doesn't want to continue in the study
		1	24	25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject states he doesn't want to continue in the study

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1056 10561152	1	27	29SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT STATED HE DOES NOT WANT TO CONTINUE HIS PARTICIPATION IN THE STUDY.
		1	27	29SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT STATED HE DOES NOT WANT TO CONTINUE HIS PARTICIPATION IN THE STUDY.
	C4591001 1056 10561245	2	93	08JAN2021	VACCINATION	LOST TO FOLLOW-UP	After multiple unsuccessful TCs to Pt. and emergency contact, and a Certified letter, Pt. was D/C.
		2	93	08JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	After multiple unsuccessful TCs to Pt. and emergency contact, and a Certified letter, Pt. was D/C.
	C4591001 1056 10561253	2	32	05NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT MOVED OUT OF STATE AND HE IS UNABLE TO CONTINUE PARTICIPATING IN THE STUDY.
		2	32	05NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT MOVED OUT OF STATE AND HE IS UNABLE TO CONTINUE PARTICIPATING IN THE STUDY.
	C4591001 1056 10561293	1	50	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
		1	50	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
	C4591001 1056 10561361	1	72	09DEC2020	VACCINATION	LOST TO FOLLOW-UP	AFTER MANY ATTEMPTS TO CONTACT THIS SUBJECT AND A CERTIFIED LETTER SENT, PI DECIDED TO D/C PT.
		1	72	09DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	AFTER MANY ATTEMPTS TO CONTACT THIS SUBJECT AND A CERTIFIED LETTER SENT, PI DECIDED TO D/C PT.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1056 10561372	1	38	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
		1	38	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
	C4591001 1056 10561392	2	73	13JAN2021	VACCINATION	LOST TO FOLLOW-UP	Subject was discontinued from study after several unsuccessful TC and a Certified Letter.
		2	73	13JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was discontinued from study after several unsuccessful TC and a Certified Letter.
	C4591001 1056 10561395	1	25	29OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT MOVED TO ANOTHER TOWN
		1	25	29OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject moved out of town.
	C4591001 1056 10561411	2	75	08JAN2021	VACCINATION	LOST TO FOLLOW-UP	After multiple unsuccessful TCs to Pt. and emergency contact, and a Certified letter, Pt. was D/C.
		2	75	08JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	After multiple unsuccessful TCs to Pt. and emergency contact, and a Certified letter, Pt. was D/C.
	C4591001 1056 10561414	1	65	09DEC2020	VACCINATION	LOST TO FOLLOW-UP	AFTER MANY ATTEMPTS TO CONTACT THIS SUBJECT AND A CERTIFIED LETTER SENT, PI DECIDED TO D/C PT.
		1	65	09DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	AFTER MANY ATTEMPTS TO CONTACT THIS SUBJECT AND A CERTIFIED LETTER SENT, PI DECIDED TO D/C PT.
	C4591001 1056 10561445	2	136	11MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the subject contacted us by phone to inform us about her desire to withdraws her consent.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1056 10561452	1	63	09DEC2020	VACCINATION	LOST TO FOLLOW-UP	AFTER MANY ATTEMPTS TO CONTACT THIS SUBJECT AND A CERTIFIED LETTER SENT, PI DECIDED TO D/C PT.
		1	63	09DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	AFTER MANY ATTEMPTS TO CONTACT THIS SUBJECT AND A CERTIFIED LETTER SENT, PI DECIDED TO D/C PT.
	C4591001 1056 10561477	2	95	04FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECEIVED A VACCINE OUTSIDE THE STUDY.
	C4591001 1056 10561511	2	103	12FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject informed us he no longer wanted to continue in the study.
	C4591001 1056 10561516	1	87	08JAN2021	VACCINATION	LOST TO FOLLOW-UP	After multiple unsuccessful TCs to Pt. and emergency contact, and a Certified letter, Pt. was D/C.
		1	87	08JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	After multiple unsuccessful TCs to Pt. and emergency contact, and a Certified letter, Pt. was D/C.
	C4591001 1056 10561550	1	84	11JAN2021	VACCINATION	LOST TO FOLLOW-UP	UNABLE TO CONTACT PT./EMERGENCY CONTACT, CERTIFIED LETTER SENT. PI DECIDED TO D/C PT AS A LTFU.
		1	84	11JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	UNABLE TO CONTACT PT./EMERGENCY CONTACT, CERTIFIED LETTER SENT. PI DECIDED TO D/C PT AS A LTFU.
	C4591001 1056 10561554	1	86	13JAN2021	VACCINATION	LOST TO FOLLOW-UP	Subject was discontinued from study after several unsuccessful TC and a Certified Letter.
		1	86	13JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was discontinued from study after several unsuccessful TC and a Certified Letter.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1056 10561569	1	85	13JAN2021	VACCINATION	LOST TO FOLLOW-UP	Subject was discontinued from study after several unsuccessful TC and a Certified Letter.
		1	85	13JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was discontinued from study after several unsuccessful TC and a Certified Letter.
	C4591001 1056 10561570	2	75	22JAN2021	VACCINATION	LOST TO FOLLOW-UP	AFTER SEVERAL UNSUCCESSFUL ATTEMPTS TO CONTACT PT VIA T.C. AND CERTIFIED LETTER, PI DECIDED TO D/C.
		2	75	22JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	AFTER SEVERAL UNSUCCESSFUL ATTEMPTS TO CONTACT PT VIA T.C. AND CERTIFIED LETTER, PI DECIDED TO D/C.
	C4591001 1056 10561591	1	73	06JAN2021	VACCINATION	LOST TO FOLLOW-UP	After multiple unsuccessful TCs to Pt. and emergency contact, and a Certified letter, Pt. was D/C.
		1	73	06JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	After multiple unsuccessful TCs to Pt. and emergency contact, and a Certified letter, Pt. was D/C.
	C4591001 1056 10561592	2	81	18FEB2021	VACCINATION	LOST TO FOLLOW-UP	After many attempts to contact subject, Investigator decided to discontinue Pt. as a LTFU
		2	81	18FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	After many attempts to contact subject, Investigator decided to discontinue Pt. as a LTFU
	C4591001 1056 10561601	2	57	11JAN2021	VACCINATION	LOST TO FOLLOW-UP	UNABLE TO CONTACT PT./EMERGENCY CONTACT, CERTIFIED LETTER SENT. PI DECIDED TO D/C PT AS A LTFU.
		2	57	11JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	UNABLE TO CONTACT PT./EMERGENCY CONTACT, CERTIFIED LETTER SENT. PI DECIDED TO D/C PT AS A LTFU.
	C4591001 1056 10561609	2	74	28JAN2021	VACCINATION	LOST TO FOLLOW-UP	SUBJECT WAS DISCONTINUED AS A LTFU AFTER MULTIPLE ATTEMPTS TO CONTACT HIM.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		2	74	28JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT WAS DISCONTINUED AS A LTFU AFTER MULTIPLE ATTEMPTS TO CONTACT HIM.
	C4591001 1056 10561634	2	76	01FEB2021	VACCINATION	LOST TO FOLLOW-UP	AFTER MANY UNSUCCESSFUL ATTEMPTS TO CONTACT PT. INCLUDING CERTIFIED LETTER PI DECIDED TO D/C SUBJECT
		2	76	01FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	AFTER MANY UNSUCCESSFUL ATTEMPTS TO CONTACT PT. INCLUDING CERTIFIED LETTER PI DECIDED TO D/C SUBJECT
	C4591001 1056 10561636	1	14	11NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject tested positive for COVID-19 during the COVID-19 illness visit (Onsite swab).
	C4591001 1057 10571031			18AUG2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	met delay criteria, reported by subject after subject was randomized, discontinued prior to vaccine
	C4591001 1057 10571050	2	133	19JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECEIVED VACCINE OUTSIDE OF THE STUDY.
	C4591001 1057 10571177	2	113	25JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1057 10571198	2	98	13JAN2021	FOLLOW-UP	OTHER	patient moved out of state and received Pfizer vaccine out in the community
	C4591001 1057 10571201	2	98	19JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECEIVED VACCINE OUTSIDE OF THE STUDY.
	C4591001 1057 10571202	2	145	01MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	MOVING OUT OF STATE

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1057 10571211			18SEP2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	subject was randomized but failed to meet entry criteria, no vaccine was given
	C4591001 1057 10571212			18SEP2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	subject was randomized and then failed to meet criteria, no vaccine was administered
	C4591001 1057 10571215			18SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	refused further study procedures
	C4591001 1057 10571216	2	30	10NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	MOVED TO SAN FRANCISCO
		2	30	10NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	MOVED TO SAN FRANCISCO
	C4591001 1057 10571227	2	120	08FEB2021	REPEAT SCREENING 1	OTHER	PATIENT REFUSED VACCINE AS HE STATED HE CHANGED HIS MIND AT TIME OF VISIT
	C4591001 1057 10571230	2	56	23DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	PERSONAL REASONS
		2	56	23DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	PERSONAL REASONS
	C4591001 1057 10571248	1	36	30OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject refused to return for Visit 2, withdrew consent, No adverse events reported
		1	36	30OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent from further study participation
	C4591001 1057 10571268			06OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	w/d consent

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1057 10571279	2	120	22FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	NO LONGER INTERESTED IN PARTICIPATING BEING UNBLINDED OR ANY OTHER VACCINES
	C4591001 1057 10571319	2	47	28DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrew consent due to transportation issues
		2	47	28DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrew consent due to transportation issues
	C4591001 1066 10661121	2	147	11FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received moderna vaccine
	C4591001 1066 10661198	1	107	22DEC2020	VACCINATION	LOST TO FOLLOW-UP	unable to reach patient after several attempts and certified letter
		1	107	22DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	unable to reach subject after several attempts and certified letter
	C4591001 1066 10661332	1	56	08DEC2020	VACCINATION	LOST TO FOLLOW-UP	unable to reach subject after several phone attempts and certified letter
		1	56	08DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	unable to reach subject after several phone attempts and certified letter
	C4591001 1066 10661335			14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent to participate
	C4591001 1066 10661396	1	22	22DEC2020	VACCINATION	OTHER	unblinded to assess eligibility for vaccination
	C4591001 1071 10711021	2	171	17FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW UP

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1071 10711034	2	193	12MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW UP
	C4591001 1071 10711095	1	61	24OCT2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT IS LOST TO FOLLOW UP
	C4591001 1071 10711162	1	61	24OCT2020 11SEP2020	FOLLOW-UP FOLLOW-UP	LOST TO FOLLOW-UP WITHDRAWAL BY SUBJECT	SUBJECT IS LOST TO FOLLOW UP SUBJECT WITHDREW CONSENT
	C4591001 1071 10711164	2	129	11FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW UP
	C4591001 1071 10711175	2	114	28JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT LOST TO FOLLOW UP
	C4591001 1071 10711185	1	60	16NOV2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RETURNED FOR VISIT 2
	C4591001 1071 10711211	1	60	16NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT LOST TO FOLLOW UP
	C4591001 1071 10711211	1	32	05NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT TO 2ND INJECTION BUT WILL RETURN FOR FOLLOW UP VST
	C4591001 1071 10711224	1	43	16NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1071 10711224	2	106	17FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW UP
	C4591001 1071 10711230	2	48	21DEC2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT LOST TO FOLLOW UP

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		2	48	21DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT PER SITE SOP, RETURNED AS UNDELIVERABLE
	C4591001 1071 10711234	2	91	09FEB2021	VACCINATION	PROTOCOL DEVIATION	SUBJECT RECEIVED OTHER COVID VACCINATION
		2	118	08MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECEIVED OTHER COVID VACCINATION
	C4591001 1071 10711235	1	50	08DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT REFUSED SECOND INJECTION AND FURTHER STUDY PROCEDURES
		1	50	08DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT DECLINED SECOND INJECTION AND FURTHER STUDY PROCEDURES
	C4591001 1071 10711237	1	40	01DEC2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT LOST TO FOLLOW UP
		1	40	01DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT LOST TO FOLLOW UP
	C4591001 1072 10721051	1	12	06SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	diagnosis COVID-19 exclusion 5
	C4591001 1072 10721099	2	148	23FEB2021	REPEAT SCREENING 1	OTHER	Subject delayed on vaccination due to medication
	C4591001 1073 10731022	2	163	03FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Not willing to continue
	C4591001 1073 10731038	1	37	10SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject was Discontinue
		1	37	10SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Discontinue

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1073 10731067	2	157	05FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdrew Consent
	C4591001 1073 10731120	2	94	18DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject in medical field was offered vaccine before site was able to over IP. Withdrew consent.
	C4591001 1077 10771077	2	119	06JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	(b) (6) BECAME AN EMPLOYEE AT (b) (6) AND WILL NO LONGER CONTINUE IN THE STUDY.
	C4591001 1077 10771243	2	127	11MAR2021	VACCINATION	LOST TO FOLLOW-UP	Subject was contacted multiple times to reschedule appt 3 with no response.
		2	127	11MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT CONTACTE ATTEMPTED MULTIPLE TIMES TO RESCHEDULE APPOINTMENT 3 WITH NO ANSWER.
	C4591001 1079 10791004	1	23	20AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/ADENOCARCINOMA GASTRIC
		1	30	27AUG2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/ADENOCARCINOMA GASTRIC
	C4591001 1079 10791040	2	45	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject has not returned calls, emails or letters
		2	45	07OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is lost to follow up
	C4591001 1079 10791109	2	75	16NOV2020	VACCINATION	LOST TO FOLLOW-UP	lost to follow up
		2	75	16NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up
	C4591001 1079 10791130	1	1	17AUG2020	VACCINATION	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT/WRONG PRODUCT ADMINISTERED

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1079 10791153	2	175	04MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrawn
	C4591001 1079 10791253	1	67	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	patient unresponsive
		1	67	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	patient unresponsive
	C4591001 1080 10801019	2	155	01FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Patient received vaccine outside of the study.
	C4591001 1080 10801055	2	105	21DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Patient was vaccinated for COVID by her employer prior to being unblinded
	C4591001 1080 10801205	2	139	24FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Patient is a LTFU. He moved to another state and will not contact the site back to transfer.
	C4591001 1081 10811006	2	142	19JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	no-showed for V101, never returned calls/emails. unk if rec'd outside covid vax
	C4591001 1081 10811071	1	48	05OCT2020	VACCINATION	LOST TO FOLLOW-UP	lack of follow-up, does not return calls & had multiple no show appointments
		1	48	05OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	unable to reach subj, multiple no-show appts. This was the last scheduled visit that was a no-show.
	C4591001 1081 10811087	2	123	15JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	received vax at job & refused to continue. then retracted that he rec'd vax.
	C4591001 1081 10811094	2	96	18DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent, via an email, since she was offered vax @ work. She would not return calls

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1081 10811105			26AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1081 10811114	2	94	18DEC2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	Participant met exclusion criterion #16
	C4591001 1081 10811186	2	81	18DEC2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	Participant met exclusion criterion #16
	C4591001 1081 10811194	2	37	04NOV2020	FOLLOW-UP	DEATH	DEATH/MYOCARDIAL INFARCTION
	C4591001 1082 10821013			03AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject was randomized but left site prior to receiving vaccination.
	C4591001 1082 10821077	1	22	28AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	scheduling conflicts. live out of state.
		1	22	28AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1082 10821078	1	22	28AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	scheduling conflicts. live out of state.
		1	22	28AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1082 10821145	2	30	23OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent due to occupation
		2	30	23OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent due to occupation

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1082 10821149	2	63	24NOV2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/MALIGNANT MELANOMA
	C4591001 1082 10821221	1	21	19NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1082 10821224	2	102	01MAR2021	VACCINATION	LOST TO FOLLOW-UP	subject did not respond to site contact attempts. certified letter returned, unclaimed.
		2	102	01MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	subject did not respond to site contact attempts. certified letter returned, unclaimed.
	C4591001 1083 10831029	1	20	23AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/ATRIAL FIBRILLATION
	C4591001 1083 10831060	1	9	14AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DIVERTICULAR PERFORATION
	C4591001 1083 10831068	2	141	18JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent and recieved no subject has not contacted site
	C4591001 1083 10831141	1	34	23SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject no longers wants to participate in the study subject was offered safety F/U Sub Declined
		1	162	29JAN2021	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1083 10831154	2	129	20JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject WOC not wanting to wait for his qualifying Tier per CDC/ Sponsor Guidelines
	C4591001 1083 10831162	2	164	26FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received outside COVID-19 Vaccine 21DEC2020

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1083 10831187	2	28	22OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT MOVE OUT OF STATE
		2	28	22OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	22OCT2020 subject was contacted for V3 Appointment reminder 23OCT2020 and verbally withdrew consent
	C4591001 1083 10831219	2	37	05NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject was contacted to reschedule Visit 3 and he withdrew consent
		2	37	05NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	05NOV2020 After multiple attempts to contact subj to reschedule V3 subj returned call and WC
	C4591001 1083 10831242	2	98	05JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received non-study coronavirus vaccination
	C4591001 1083 10831252	2	85	05JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Received outside of the study covid-19 vaccine
	C4591001 1083 10831284	2	111	02MAR2021	OPEN LABEL TREATMENT	PROTOCOL DEVIATION	Subject did not disclose she had already received outside vaccine until after 30min post assessment
	C4591001 1084 10841009	2	112	07DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent, no response from subject
	C4591001 1084 10841017	2	117	18DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	subject withdrew due to receiving vaccine at work
	C4591001 1084 10841023	2	149	21JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject stated that she no longer wishes to participate in the study.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1084 10841035	1	22	24AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject does not want to do study anymore; now engaged and wants to start a family
		1	22	24AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew consent because subject wants to start a family
	C4591001 1084 10841057	1	35	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	subject never answered phone calls; certified letter sent
		1	35	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject never answered phone calls; certified letter sent
	C4591001 1084 10841061	2	124	29DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Moderna vaccination at work.
	C4591001 1084 10841062	2	130	07JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	subject has not returned or followed up with site or CRC for visits
	C4591001 1084 10841119	2	38	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	certified letter sent
		2	38	07OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject LTFU; certified letter sent
	C4591001 1084 10841137	2	108	18DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Received vaccine at work on 18Dec2020
	C4591001 1084 10841156	2	130	11JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Moderna COVID-19 vaccine
	C4591001 1084 10841187	2	65	12NOV2020	VACCINATION	LOST TO FOLLOW-UP	not able to reach subject, certified letter went out.
		2	65	12NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	not able to reach subject, certified letter went out.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1084 10841241	2	122	08JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Moderna COVID-19 vaccine on 24Dec2020
	C4591001 1084 10841272	1	32	22SEP2020	VACCINATION	LOST TO FOLLOW-UP	LTFU
		1	32	22SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	LTFU
	C4591001 1084 10841290	2	105	27DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received MODERNA COVID-19 VACCINE
	C4591001 1084 10841333	2	27	28OCT2020	VACCINATION	OTHER	subject was initially thought to be LTFU on this date, but rejoined for open label
	C4591001 1084 10841358	2	86	22DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received COVID-19 vaccine outside of study
	C4591001 1084 10841432	2	40	24NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject has not returned calls from CRC, certified letter was sent.
		2	40	24NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject has not returned calls from CRC, certified letter was sent.
	C4591001 1084 10841439	2	92	11JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received vaccine outside of study
	C4591001 1084 10841450	2	43	25NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject has not returned calls to CRC, certified letter will be sent today.
		2	43	25NOV2020	FOLLOW-UP	OTHER	subject is a front line worker at a hospital and was no longer able to make it for her visits.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1084 10841456	2	84	07JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Moderna Covid-19 vaccination at work.
	C4591001 1084 10841480	2	67	07JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject prefers to have vaccine through employer subject dropped
	C4591001 1084 10841512	2	119	09MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject will not be available for follow-up appointments.
	C4591001 1085 10851064	2	152	01FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1085 10851069	2	110	21DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew consent
	C4591001 1085 10851081	2	87	30NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject no longer interested in the study.
		2	87	30NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Site received call call from patient stating she was no longer interested in the study.
	C4591001 1085 10851129	2	168	24FEB2021	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/EXPOSURE DURING PREGNANCY
	C4591001 1085 10851137	2	104	23DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew Consent
	C4591001 1085 10851237	2	108	09JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew consent

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1085 10851244	2	97	30DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Received vaccine elsewhere
	C4591001 1085 10851286	1	24	02OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion #5
	C4591001 1085 10851287	2	116	25JAN2021	FOLLOW-UP	PROTOCOL DEVIATION WITHDRAWAL BY SUBJECT	Subject was vaccinated outside of the study. Withdrew consent
	C4591001 1085 10851332	1	37	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	Contacted multiple times. Sent certified letter on 16Nov2020. Letter was returned to site last week.
	C4591001 1087 10871066	2	184	20OCT2020 02MAR2021	FOLLOW-UP FOLLOW-UP	LOST TO FOLLOW-UP PROTOCOL DEVIATION	Patient unreachable. Certified letter mailed. COVID-19 Vaccine Received outside C4591001 study
	C4591001 1087 10871085	2	13	20SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Pt moved to another State for job. Closest Site 1+ hr away from pt's new location. Withdrew consent.
	C4591001 1087 10871089	2	13	20SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt moved to another State for job. Closest Site 1+ hr away from pt's new location. Withdrew consent.
	C4591001 1087 10871089	1	19	04SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criteria #5
	C4591001 1087 10871146	2	124	11JAN2021	FOLLOW-UP	OTHER	Subject moving to Florida and closest Site < 2 hrs away. Subject opted to withdraw from study.
	C4591001 1087 10871209	1	7	31AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject has met exclusion #5

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	38	01OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject chose to withdraw from study because felt no longer necessary due to positive COVID dx.
	C4591001 1087 10871279	2	156	23FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject is unwilling to return for vaccine if in the placebo group.
	C4591001 1087 10871336	1	61	02NOV2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up
		1	61	02NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1087 10871354	1	10	17SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/MYALGIA
		1	10	17SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/MYALGIA
	C4591001 1087 10871356	1	54	31OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up.
		1	54	31OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up.
	C4591001 1087 10871363	2	56	23NOV2020	VACCINATION	LOST TO FOLLOW-UP	lost to follow up
		2	56	23NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up.
	C4591001 1087 10871525	2	131	23FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject unwilling to return for vaccination.
	C4591001 1087 10871557	1	23	05NOV2020	VACCINATION	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY
	C4591001 1087 10871562	1	100	21JAN2021	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	100	21JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up.
	C4591001 1089 10891050	2	197	10MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1089 10891054	2	60	23OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient withdrew consent
	C4591001 1089 10891076	1	22	27AUG2020	VACCINATION	LOST TO FOLLOW-UP	8/25-# out of service, sent email 8/27-no response, sent certified letter
		1	22	27AUG2020	FOLLOW-UP	LOST TO FOLLOW-UP	number invalid and sent certified letter. no response
	C4591001 1089 10891158	1	44	02OCT2020	VACCINATION	OTHER	site was notified that subject has been incarcerated and will not be able to complete study visit
		1	44	02OCT2020	FOLLOW-UP	OTHER	site was notified that subject has been incarcerated and will not be able to complete study visit
	C4591001 1089 10891179	2	157	18FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject moved, withdrew consent
	C4591001 1089 10891182	1	91	23NOV2020	VACCINATION	LOST TO FOLLOW-UP	patient is lost to follow-up, no response on calls or certified letter
		1	91	23NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject is lost to follow up, 3 calls and certified letter sent
	C4591001 1089 10891186	2	42	29OCT2020	VACCINATION	LOST TO FOLLOW-UP	3 calls-no response, certified letter sent
	C4591001 1089 10891207	2	162	26FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	3 phone call attempts, certified letter sent and returned.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1089 10891213	2	47	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	3 calls-no response, certified letter sent
		2	47	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Patient has been contacted via phone 3x and certified letter was sent with o response.
	C4591001 1089 10891227	2	155	26FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	3 phone call attempts have ben made, certified letter sent and returned to site.
	C4591001 1089 10891231	2	39	29OCT2020	VACCINATION	LOST TO FOLLOW-UP	3 calls-no response, certified letter sent
		2	39	29OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	patient withdrew consent
	C4591001 1089 10891289	2	79	19DEC2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/ACUTE HEPATIC FAILURE
	C4591001 1089 10891294	2	151	01MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	3 phone call attempts and certified letter sent, certified letter came back as not deliverable
	C4591001 1089 10891334	2	141	26FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	3 phone call attempts have ben made, certified letter sent and returned to site.
	C4591001 1089 10891346			22SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent prior to receiving vaccine
	C4591001 1089 10891350	2	124	15FEB2021	VACCINATION	LOST TO FOLLOW-UP	lm 3x certified letter sent
		2	124	15FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	3 attempts and certified letter sent LTFU
	C4591001 1089 10891351			25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent, and left office prior to vaccination

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1090 10901047	2	45	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	Pt was not reachable the last 2 weeks. HE is in prison per his sister. Pt will be discontinued.
		2	45	07OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	pt in prison
	C4591001 1090 10901052	2	158	28JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	planned to receive a non-study covid-19 vaccine outside of study
	C4591001 1090 10901067	2	122	23DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	unblinded per subject request
	C4591001 1090 10901068	1	29	02SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	pt is not willing to come to any m visits
		1	29	02SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject no longer interested in study
	C4591001 1090 10901073	2	198	09MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient not willing to come in for mo 6 or any other study visits.
	C4591001 1090 10901328	2	63	25NOV2020	VACCINATION	LOST TO FOLLOW-UP	pt did not come for V3 and was unresponsive to calls and certified letter
		2	63	25NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Pt did not come for V3 and not responsive to calls or certified letter
	C4591001 1090 10901379	1	54	02NOV2020	VACCINATION	LOST TO FOLLOW-UP	pt never contacted us to reschedule V2
		1	54	02NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	unable to contact
	C4591001 1090 10901463	2	63	17DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject requested to be unblinded before eligible

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1090 10901507	1	20	04NOV2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/URTICARIA
	C4591001 1090 10901517	2	49	29DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject requested to be unblinded before eligibility
	C4591001 1090 10901539	2	34	16DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject wanted to be unblinded
	C4591001 1090 10901551	2	31	17DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject requested to be unblinded
	C4591001 1091 10911039	1	50	22SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrew consent to future visits
		1	50	22SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrew consent to further visits
	C4591001 1091 10911077	1	22	27AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Patient agrees to stay in the trial for follow up but denied second vaccination.
	C4591001 1091 10911083	1	23	28AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Did not want to come to scheduled visits
		1	23	28AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject no longer wanted to come to study appointments
	C4591001 1091 10911091	2	113	21DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject was vaccinated outside of study
	C4591001 1091 10911122	2	169	16FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received moderna vaccine

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1091 10911215	2	142	10FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Study subject received Moderna Vaccine
	C4591001 1091 10911333	2	29	09NOV2020	VACCINATION	PROTOCOL DEVIATION	Subject was no show for appointment. Site reached out several times and no response.
	C4591001 1091 10911352	1	23	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject was a NCNS for his V2 today. Stated over the phone he would like to withdraw consent
		1	23	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject was a NCNS for his V2. Stated over the phone he would like to withdraw consent
	C4591001 1092 10921055	2	138	29JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is lost to follow-up
	C4591001 1092 10921080	1	22	16SEP2020	VACCINATION	OTHER	Incarcerated 09Sep2020
		1	22	16SEP2020	FOLLOW-UP	OTHER	Incarcerated
	C4591001 1092 10921082	2	35	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	unable to make contact with subject
		2	35	20OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is Lost to follow up
	C4591001 1092 10921128			01SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt withdrew consent due to anxiety of having blood drawn
	C4591001 1092 10921188	2	154	08MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject canceled V101, site made 4 attempts to reschedule and sent letter via mail
	C4591001 1092 10921249	1	1	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject No Show for V2 and is Lost to Follow Up

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1093 10931055	1	1	20OCT2020 31AUG2020	FOLLOW-UP FOLLOW-UP	LOST TO FOLLOW-UP NO LONGER MEETS ELIGIBILITY CRITERIA	Subject No Show for V2, subject Lost to Follow Up UNABLE TO OBTAIN BLOOD FROM SUBJECT.
	C4591001 1093 10931058	1	25	18SEP2020	VACCINATION	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY
		1	77	09NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was lost to follow up./EXPOSURE DURING PREGNANCY
	C4591001 1093 10931065	1	81	14NOV2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT WAS SENT A CERTIFIED LETTER AND WAS UNABLE TO BE CONTACTED MULTIPLE TIMES.
		1	81	14NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT WAS SENT A CERTIFIED LETTER AND WAS UNABLE TO BE CONTACTED MULTIPLE TIMES.
	C4591001 1093 10931072	1	81	14NOV2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT WAS SENT A CERTIFIED LETTER AND WAS UNABLE TO BE CONTACTED MULTIPLE TIMES.
		1	81	14NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT WAS SENT A CERTIFIED LETTER AND WAS UNABLE TO BE CONTACTED MULTIPLE TIMES.
	C4591001 1093 10931094	1	76	14NOV2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT WAS SENT A CERTIFIED LETTER AFTER MULTIPLE ATTEMPTS TO CONTACT THEM.
		1	76	14NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT WAS SENT A CERTIFIED LETTER AFTER MULTIPLE ATTEMPTS TO CONTACT THEM.
	C4591001 1093 10931100	2	79	10DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT STATED THEY WERE NOW TOO BUSY WITH WORK TO TRAVEL TO APPOINTMENTS.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		2	79	10DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT STATED THEY WERE NOW TOO BUSY WITH WORK TO TRAVEL TO APPOINTMENTS.
	C4591001 1093 10931129	2	68	11DEC2020	VACCINATION	PROTOCOL DEVIATION	Visit 3 was missed.
	C4591001 1093 10931216	2	33	22DEC2020	VACCINATION	PROTOCOL DEVIATION	SUBJECT RECEIVED AN OUTSIDE STUDY COVID VACCINATION.
		2	33	22DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECEIVED AN OUTSIDE STUDY COVID VACCINATION.
	C4591001 1094 10941167	2	124	22FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received the non study covid 19 vaccine before being discontinued or withdrawing from study
	C4591001 1094 10941169	2	120	23FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received the non study covid 19 vaccine before being discontinued or withdrawing from study
	C4591001 1095 10951031	2	114	15DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Participant received Pfizer COVID-19 vaccine through employer
	C4591001 1095 10951056	1	35	08SEP2020	VACCINATION	OTHER	not able to meet study requirements due to work schedule
		1	35	08SEP2020	FOLLOW-UP	OTHER	Participant not able to continue in study at this time. Participant did not withdraw consent
	C4591001 1095 10951141	1	22	16SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DIABETIC FOOT
		1	22	16SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/DIABETIC FOOT

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1095 10951144	2	23	22DEC2020	VACCINATION	OTHER	participant proceeded to crossover prior to Vt. 3, group 1A
	C4591001 1095 10951177	2	101	01JAN2021	VACCINATION	LOST TO FOLLOW-UP	Certified letter sent
		2	101	01JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	certified letter sent
	C4591001 1095 10951270	2	1	28OCT2020	VACCINATION	LOST TO FOLLOW-UP	certified letter sent
		2	1	28OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	certified letter sent
	C4591001 1095 10951271	2	1	28OCT2020	VACCINATION	LOST TO FOLLOW-UP	certified letter sent
		2	1	28OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	certified letter sent
	C4591001 1096 10961012	2	139	26JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Received monoclonal antibody/placebo treatment through clinical trial
	C4591001 1096 10961026	2	110	22DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Covid-19 Vaccination outside of study
	C4591001 1096 10961031	1	22	04SEP2020	VACCINATION	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY
	C4591001 1096 10961036	2	175	02MAR2021	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	inclusion/exclusion criteria not met/DEPRESSION SUICIDAL
	C4591001 1096 10961076	2	125	12JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject will receive Covid-19 Vaccination outside of the study.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1096 10961081	1	54	12OCT2020	VACCINATION	LOST TO FOLLOW-UP	LTFU, unresponsive to contact attempts
		1	54	12OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	site unable to contact subject after multiple attempts and certified letter sent
	C4591001 1096 10961109	2	103	23DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Covid-19 Vaccination Outside of study
	C4591001 1096 10961141	1	22	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criteria #5
	C4591001 1096 10961216	2	92	23DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Covid-19 Vaccination outside of the study
	C4591001 1096 10961256	2	145	16FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received COVID vaccine outside of trial
	C4591001 1096 10961276	1	21	25SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	due to moving out of town unexpectedly
		1	21	25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	due to moving out of town unexpectedly
	C4591001 1096 10961318	2	82	23DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Covid-19 Vaccination outside of study
	C4591001 1096 10961321	1	22	03OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject met exclusion #1 on visit 2 (suicidal ideation) so no vaccine was administered
	C4591001 1096 10961344	1	80	04DEC2020	VACCINATION	LOST TO FOLLOW-UP	multiple calls made to subject and certified letter sent.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	80	04DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject was lost to follow up
	C4591001 1096 10961388	1	21	29OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject was diagnosed with COVID between vaccination one and vaccination two
	C4591001 1098 10981001	1	31	17SEP2020	VACCINATION	LOST TO FOLLOW-UP	Lost to followup
		1	31	17SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter was sent. Site is unable to contact the subject. Thanks.
	C4591001 1098 10981029	1	22	11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject wanted to be discontinued from the study for unknown reasons.
		1	22	11SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject inform, it is due to wellbeing
	C4591001 1098 10981106	2	163	05MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Discontinued due to loss to follow up.
	C4591001 1098 10981200	1	46	05NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject called multiple times and certified letter was sent. No response from subject
		1	46	05NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject called multiple times and certified letter was sent. No response from subject.
	C4591001 1098 10981219	1	43	05NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdraw by subject due to no longer wanting to take part in the study.
		1	43	05NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdraw by subject due to no longer wanting to take part in the study.
	C4591001 1098 10981224	2	82	04JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject got Pfizer vaccine at work.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1098 10981243	2	139	08MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Discontinued
	C4591001 1098 10981244	2	84	12JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject has been discontinued due to lost of followup.
	C4591001 1098 10981266	2	35	16DEC2020	VACCINATION	LOST TO FOLLOW-UP	3 attempts to get hold of the pt. Sent the certified letter but subject didnot answer.
		2	35	16DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	3 attempts to get hold of the pt. Sent the certified letter but subject didnot answer.
	C4591001 1101 11011024	1	21	29SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	the subject was diagnoses with COVID between vaccination one and vaccination two
	C4591001 1107 11071013	2	162	01FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Moderna vaccine
	C4591001 1107 11071065	2	84	18NOV2020	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1107 11071074	2	74	12NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT ON 12NOV2020
	C4591001 1109 11091030	2	37	23SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT CALLED TO WITHDRAW FROM TRIAL DUE TO TRANSPORTATION ISSUES AS WELL AS BEING TO BUSY.
		2	37	23SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT CALLED TO WITHDRAW FROM TRIAL DUE TO TRANSPORTATION ISSUES AS WELL AS BEING TO BUSY.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1109 11091041	2	133	29DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject was unblinded by own request not eligible for unblinding by EUA
	C4591001 1109 11091059	1	40	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RETURNED PHONE CALLS OR RESPOND TO CERTIFIED LETTER.
		1	40	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RETURNED PHONE CALLS OR RESPOND TO CERTIFIED LETTER.
	C4591001 1109 11091066	2	176	10FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wanted to participate
	C4591001 1109 11091068	1	40	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RETURNED NUMEROUS CALLS OR CERTIFIED LETTER SENT TO HIM.
		1	40	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO CALLS OR CERTIFIED LETTER.
	C4591001 1109 11091126	2	120	22DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdraw by subject
	C4591001 1109 11091127	1	37	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO MULTIPLE CALLS AND CERTIFIED LETTER SENT TO HER
		1	37	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVE RESPONDED TO CALLS OR CERTIFIED LETTER SENT TO HER.
	C4591001 1109 11091148	2	33	26SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT CALLED AND WITHDREW CONSENT
		2	33	26SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT CALLED AND WITHDREW CONSENT

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1109 11091197	2	129	07JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1109 11091234	1	25	08SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	WORK HAD GOTTEN TOO BUSY WITH OPENING BACK UP AND SHE WAS UNABLE TO CONTINUE HER PARTICIPATION.
		1	25	08SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	WORK HAD GOTTEN TOO BUSY WITH OPENING BACK UP AND SHE WAS UNABLE TO CONTINUE HER PARTICIPATION.
	C4591001 1109 11091275	2	125	11JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject withdrew due to getting vaccine at another location.
	C4591001 1109 11091335	1	43	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO MULTIPLE CALLS AND CERTIFIED LETTER SENT TO HER
		1	43	07OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO MULTIPLE CALLS AND CERTIFIED LETTER SENT TO HER
	C4591001 1109 11091349			28AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject randomized in error.
	C4591001 1109 11091352	2	117	13JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wanted to participate in study.
	C4591001 1109 11091419	2	40	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not respond to multiple phone calls or certified letter.
		2	40	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not respond to multiple phone calls or certified letter.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1109 11091478	1	29	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
		1	29	07OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO MULTIPLE CALLS AND CERTIFIED LETTER SENT
	C4591001 1109 11091496	2	88	28DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	No longer wanted to participate
	C4591001 1109 11091515	1	30	14OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject never returned for visit, responded to call or certified letter sent.
		1	30	14OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject never returned for visit, responded to call or certified letter sent.
	C4591001 1109 11091547	1	63	01DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent
		1	63	01DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wanted to participate in study
	C4591001 1109 11091556	1	9	12OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1110 11101010	2	63	22OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not comply with inclusion criteria #2.
		2	63	22OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not comply with inclusion criteria #2.
	C4591001 1110 11101038	1	35	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject was contact over the phone 3 times and a certified letter was sent. Subject never reply.
		1	35	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow is status, subject has been withdrawn from trial.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1110 11101039	1	35	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	subject failed to contact site after many calls and certified letter.
		1	35	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not respond to many phones calls from site and did not respond to certified letter fromi
	C4591001 1110 11101069	1	59	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject was called more the 3 times,was texted 2 times,email/certified letter were sent
		1	59	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	we did more than 3 attempts via phone, 1 text message, 4 emails and a certified letter.
	C4591001 1110 11101075	2	97	09DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject states is in his best interest to participate in other studies
	C4591001 1110 11101085	1	58	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject was tried to contact by phone, text, email and certified letter several times.
		1	58	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	we did 4 phone call attempts, 1 text message, 1 email and a certified letter.
	C4591001 1110 11101102	2	182	08MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject is moving to London in two weeks
	C4591001 1110 11101110	1	22	08SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		1	22	08SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1110 11101117	2	92	09DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject states is in his best interest not continue in the study

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1110 11101141	2	56	12NOV2020	VACCINATION	LOST TO FOLLOW-UP	4 attempts via phone call, 1 text message, 1 email and 1 certified letter.
		2	56	12NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	4 attempts via phone call, 1 text message, 1 email and 1 certified letter.
	C4591001 1110 11101154	1	21	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject was contacted over the phone because she missed visit 2 and subject withdraw consent.
		1	21	17SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent verbally over the phone.
	C4591001 1110 11101155	1	21	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject was contacted over the phone because she missed visit 2 and subject withdraw consent.
		1	21	17SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject verbally withdrew consent.
	C4591001 1110 11101156	1	96	01DEC2020	VACCINATION	LOST TO FOLLOW-UP	Subject was attempt to contact by 2 text messages, 1 certified letter, 1 email and 8 phone call.
		1	96	01DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was attempt to contact by 2 text messages, 1 certified letter, 1 email and 8 phone call.
	C4591001 1110 11101177	2	156	24FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Moderna vaccine outside of study trial.
	C4591001 1110 11101229	1	21	30SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject meets exclusion criterion #5
	C4591001 1110 11101244	2	122	03FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject do not want to continue in the study

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1110 11101247	1	22	06OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject WICF because he is unable to continue with the visit due to work.
		1	22	06OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject WICF because he is unable to continue with the visit due to work.
	C4591001 1110 11101250	1	22	06OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject did not provide a reason to be discontinued from the study.
		1	22	06OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject did not provide a reason to be discontinued from the study.
	C4591001 1110 11101326	2	83	12JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject wants to be discontinued from the study because she can not comply with the study schedule
	C4591001 1110 11101333	1	35	05NOV2020	VACCINATION	LOST TO FOLLOW-UP	we attempt 3 phone calls, 1 text message and 1 certified letter.
		1	35	05NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	we attempt 3 phone calls, 1 text message and 1 certified letter.
	C4591001 1110 11101342	1	31	05NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject sent and email, he state he will like to withdraw from the study due to a private reason.
		1	31	05NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject sent and email, he state he will like to withdraw from the study due to a private reason.
	C4591001 1110 11101380	2	38	29JAN2021	VACCINATION	WITHDRAWAL BY PARENT/GUARDIAN	Parent discontinue subject because he states subject is too busy with school.
		2	38	29JAN2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Parent discontinued subject because he states subject is too busy with school.
	C4591001 1111 11111051	2	119	22DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received COVID-19 vaccine at work. As a result, the subject is discontinued in the study.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1112 11121054	2	43	07OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent due to work schedule
		2	43	07OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew due to busy work schedule
	C4591001 1112 11121058	1	22	25AUG2020	VACCINATION	OTHER	(b) (6) now employed by (b) (6)
		1	22	25AUG2020	FOLLOW-UP	OTHER	now employed by (b) (6)
	C4591001 1112 11121062	2	132	03JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	subject rec'd vaccine at her job
	C4591001 1112 11121083	2	118	21DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received COVID-19 vaccination offered to her by employer.
	C4591001 1112 11121135	2	111	28DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject rec'd Pfizer Covid vaccine at work on 12/23/2020
	C4591001 1112 11121190	2	174	08MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject moved out of state, unable to make follow up visits
	C4591001 1112 11121192	1	34	30SEP2020	VACCINATION	LOST TO FOLLOW-UP	unable to reach subject for missed appts
		1	34	30SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Unable to contact subject for Vs 2
	C4591001 1112 11121229			04SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject left clinic after randomization and prior to vaccination
	C4591001 1112 11121243	2	97	06JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	subject rec'd vaccine outside of the trial

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1112 11121259	2	112	15FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject in for Vacc 3, unwilling to wait required 30 mins post vaccine, withdrew consent
	C4591001 1112 11121270†	1	1	08OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	unstable viral load and Hepatitis B
	C4591001 1112 11121313	2	93	11FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	not interested in getting active vaccine or participation in the study
	C4591001 1114 11141015	2	184	05MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received vaccine outside study and Requests Withdrawal
	C4591001 1114 11141029	2	45	29OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject no show to apt and no response from certified letter.
		2	45	29OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject no show to apt and no response from certified letter.
	C4591001 1114 11141037	1	54	09OCT2020	VACCINATION	LOST TO FOLLOW-UP	no show to visit 2,two times.subject no responsive to calls and voicemails and subjects emerg.contac
		1	54	09OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	no show to visit 2,two times.subject no responsive to calls and voicemails and subjects emerg.contac
	C4591001 1114 11141054	2	104	21DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received COVID-19 vaccine outside the protocol.
	C4591001 1116 11161008	2	134	28JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject received emergency use vaccine outside of study and does not want to be followed for safety
	C4591001 1116 11161012	2	134	28JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject went to outside source for vaccine.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1116 11161015			26AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent. Left site prior to IP administration.
	C4591001 1116 11161143	1	68	14NOV2020	VACCINATION	LOST TO FOLLOW-UP	Contact attempts 29SEP 30SEP 2OCT 13OCT 6NOV 9NOV
		1	68	14NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Contact attempts 29SEP 30SEP 2OCT 13OCT 6NOV 9NOV
	C4591001 1116 11161172	1	67	14NOV2020	VACCINATION	LOST TO FOLLOW-UP	Contact attempts 2OCT 5OCT 7OCT 9OCT 13OCT 23OCT 9NOV
		1	67	14NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Contact attempts 2OCT 5OCT 7OCT 9OCT 13OCT 23OCT 9NOV
	C4591001 1116 11161217	2	153	03MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject would like to get pregnant, does not want the vaccine or to continue in the study
	C4591001 1116 11161292	1	52	14NOV2020	VACCINATION	LOST TO FOLLOW-UP	Contact attempts 16OCT 22OCT 23OCT 3NOV 4NOV 9NOV 10NOV
		1	52	14NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Contact attempts 16OCT 22OCT 23OCT 3NOV 4NOV 9NOV 10NOV
	C4591001 1116 11161322	2	55	07DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW FROM STUDY
		2	55	07DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1116 11161323	2	136	26FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Attempts to Contact: 26Feb, 4Feb, 3Feb, 22Jan, 15Dec

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1116 11161326	2	122	26FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Attempted contacts: 26Feb, 3Feb, 25Jan, 22Jan, 19Jan, 7Jan, 28Dec, 21Dec
	C4591001 1117 11171014	2	115	31DEC2020	VACCINATION	LOST TO FOLLOW-UP	UNABLE TO CONTACT/SCHEDULE PARTICIPANT
		2	115	31DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	UNABLE TO CONTACT AND SCHEDULE
	C4591001 1117 11171015	2	183	10MAR2021	VACCINATION	PROTOCOL DEVIATION	OUT OF COUNTRY, EOT FOLLOW UP DONE AT V4-MONTH 6 VISIT
	C4591001 1117 11171036	2	141	28JAN2021	REPEAT SCREENING 1	NO LONGER MEETS ELIGIBILITY CRITERIA	INC 3, EXC 1
	C4591001 1117 11171138	2	31	17DEC2020	VACCINATION	PROTOCOL DEVIATION	COULD NOT GET PARTICIPANT SCHEDULED FOR V3
	C4591001 1117 11171186	1	21	26OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/SUICIDE ATTEMPT
		1	119	01FEB2021	REPEAT SCREENING 1	NO LONGER MEETS ELIGIBILITY CRITERIA	INC3 / EXC1/SUICIDE ATTEMPT
	C4591001 1117 11171190	1	6	13OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject met exclusion 5 at the time of Visit 2
	C4591001 1118 11181060	2	124	12JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	certified letter sent to subject, returned back to site unclaimed. unable to reach subject.
	C4591001 1118 11181062	2	147	04FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not respond to numerous contact attempts made by site staff

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1118 11181064	2	133	21JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew from study
	C4591001 1120 11201013	1	20	18AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject states he no longer wants to be in study
		1	20	18AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject states he no longer wants to be in study
	C4591001 1120 11201038			29OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdraw consent
	C4591001 1120 11201058	2	197	11MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdraw from study
	C4591001 1120 11201083	2	71	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	certified letter sent and moved to lost to follow up
		2	71	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject lost to follow up
	C4591001 1120 11201085	1	79	23OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject would not come in office for visit
		1	79	23OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject never showed to appointment.
	C4591001 1120 11201096	2	164	04FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject was vaccinated outside of study with Moderna
	C4591001 1120 11201104	1	50	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject states no longer wishes to be in study about to have weight lost surgery
		1	50	24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wished to be in study subject is about to have weight lost surgery

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1120 11201119	2	197	11MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer able to make appointments
	C4591001 1120 11201142	2	154	04FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdraw
	C4591001 1120 11201240	2	163	20FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject is moving out of town
	C4591001 1120 11201252			09SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was randomized, but had to leave for work. Subject never return for next appointment
	C4591001 1120 11201266	2	113	19JAN2021	FOLLOW-UP	DEATH	DEATH/LUNG CANCER METASTATIC
	C4591001 1120 11201346	2	81	29JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject moving out of state
	C4591001 1121 11211004	2	125	15JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	due to being a medical worker can no longer wait to receive trial vaccine
	C4591001 1121 11211009	2	40	22OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew due to busy schedule.
		2	40	22OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent due to busy schedule. Does not want to be FU
	C4591001 1121 11211010	2	180	11MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject asked to be withdrawn then hung up. Attempted to reach her again, she answered then hung up.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1121 11211018	2	163	23FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew to receive vaccine elsewhere
	C4591001 1121 11211025	1	22	16SEP2020	VACCINATION	OTHER	Participants significant other notified the site, participant is in jail for the foreseeable future
		1	22	16SEP2020	FOLLOW-UP	OTHER	Subject incarcerated. Subject to be dropped from the study.
	C4591001 1121 11211057	2	170	10MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject received 2 moderna doses. See non study vaccine page.
	C4591001 1121 11211059	2	92	22DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent to receive vaccine at work.
	C4591001 1121 11211061	2	109	08JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Have attempted to contact subject numerous times via telephone and certified letter. No response.
	C4591001 1121 11211067	2	100	30DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent to receive vaccine at work.
	C4591001 1121 11211087	2	164	10MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject received Moderna vaccine. 1st dose on non study vaccine page. 2nd dose not performed yet
	C4591001 1121 11211096	2	101	08JAN2021	VACCINATION	LOST TO FOLLOW-UP	Have attempted to contact subject numerous times via telephone and certified letter. No response.
		2	101	08JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Have attempted to contact subject numerous times via telephone and certified letter. No response.
	C4591001 1121 11211108	2	165	11MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	After trying to schedule subject for 2 weeks, he contacted site and asked to "opt out"

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1122 11221003	2	84	21DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	subject received COVID-19 vaccine outside of the study
	C4591001 1122 11221006			03SEP2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject randomized in error
	C4591001 1122 11221026			11SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/PRESYNCOPE
	C4591001 1122 11221038			11SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/VOMITING
	C4591001 1122 11221038	2	70	24DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received COVID-19 vaccine outside of the study.
	C4591001 1123 11231027			04AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent after randomization prior to vaccination.
	C4591001 1123 11231031	2	197	09MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	no response to certified letter
	C4591001 1123 11231051	2	43	08OCT2020	VACCINATION	OTHER	moved to hawaii
	C4591001 1123 11231069	2	43	08OCT2020	FOLLOW-UP	OTHER	Moved to Hawaii
	C4591001 1123 11231069	2	190	09MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent. Left voicemail with the patient.
	C4591001 1123 11231091	2	146	25JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1123 11231104	2	175	24FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Pt. received covid-19 vaccine
	C4591001 1123 11231137	2	1	14SEP2020	VACCINATION	LOST TO FOLLOW-UP	subject was lost to follow up after visit 2.
	C4591001 1123 11231144	1	42	30SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject was LTF following V2 Exclusion criteria #5.
	C4591001 1123 11231145	2	143	04FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	pt received non-study vaccine
	C4591001 1123 11231154	1	73	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	no response from subject after certified letter
	C4591001 1123 11231168	1	72	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	no response from subject after certified letter Pt is LTF
	C4591001 1123 11231249	2	122	05FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Pt is LTF subject received nonstudy covid-19 vaccine
	C4591001 1123 11231290	1	29	21OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent.
		1	29	21OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1123 11231301			24SEP2020	FOLLOW-UP	PROTOCOL DEVIATION	subject randomized in error
	C4591001 1123 11231313	1	13	06OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exc. criterion 5 COVID-19 positive
	C4591001 1123 11231386	1	22	09NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	exclusion no. 5 positive covid test
	C4591001 1124 11241001	2	171	17FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject in Israel and not sure when will return to United States
	C4591001 1124 11241025	2	161	09FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received Moderna vaccine through her work
	C4591001 1124 11241038	2	106	16DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew to receive Covid-19 at workplace
	C4591001 1124 11241049	1	26	11SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject not responding to any phone calls, certified letter sent
		1	26	11SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject not responding to any phone calls, certified letter sent
	C4591001 1124 11241052	2	128	14JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	received additional vaccination outside of study
	C4591001 1124 11241072	2	168	24FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject missed appointment on 2/17/21. Several attempts were made to contact subject with no success

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1124 11241084	1	10	02SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or Microbiological COVID 19 Diagnosis
		1	18	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject not interested in participating any longer
	C4591001 1124 11241103	2	97	21DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Pfizer vaccine outside of study
	C4591001 1124 11241120	2	121	15JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	received Moderna vaccine outside of study
	C4591001 1124 11241141	2	64	24NOV2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up after multiple calls and certified letter sent
		2	64	24NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
	C4591001 1124 11241167	2	136	04FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Received Moderna vaccine outside of trial
	C4591001 1124 11241199	2	91	28DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1124 11241228	2	145	01MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject has not returned any phone calls; a certified letter has been sent
	C4591001 1125 11251019	1	48	29SEP2020	VACCINATION	LOST TO FOLLOW-UP	lost to follow
		1	48	29SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	post to follow
	C4591001 1125 11251022	2	57	28OCT2020	VACCINATION	LOST TO FOLLOW-UP	patient is a lost to follow

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		2	57	28OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	patient was a lost to follow
	C4591001 1125 11251043	2	176	24FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Patient received vaccine elsewhere for COVID
	C4591001 1125 11251059	2	76	24NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject missed appt and diary entries. Multiple contact attempts with subject were not returned.
		2	76	24NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Patient deemed lost to follow
	C4591001 1125 11251142	2	154	24FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	moved from the area no longer able to make visits
	C4591001 1125 11251159	1	1	03SEP2020	VACCINATION	LOST TO FOLLOW-UP	attempted to contact patient and sent certified letter with no response back
		1	1	03SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	patient is a lost to follow
	C4591001 1125 11251160	1	33	05OCT2020	VACCINATION	LOST TO FOLLOW-UP	Patient is a lost to follow
		1	33	05OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow
	C4591001 1125 11251162	2	58	24NOV2020	VACCINATION	LOST TO FOLLOW-UP	unable to reach patient after multiple attempts and certified letter
		2	58	24NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts to schedule visit 3 and certified letter sent on 05/NOV/2020 with no response back
	C4591001 1125 11251238	1	12	02NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Patient tested positive for Covid-19, EXC #5
	C4591001 1125 11251243	1	2	09DEC2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/HEADACHE

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	2	09DEC2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/INJECTION SITE PAIN
	C4591001 1126 11261017	2	150	28JAN2021	OPEN LABEL TREATMENT	ADVERSE EVENT	ADVERSE EVENT/ALLERGY TO VACCINE
	C4591001 1126 11261045	2	104	23DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECEIVED PFIZER COVID19 VACCINE OUTSIDE OF STUDY ON 17DEC2020
	C4591001 1126 11261074			25AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	During enrollment, after consent signed, inc/exc criteria reviewed, serology/nasal swab completed
	C4591001 1126 11261080	2	112	05JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject got vaccinated with COVID-19 vaccine outside of the study.
	C4591001 1126 11261135	2	91	23DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT VACCINATED OUTSIDE OF STUDY PROTOCOL DESPITE APPT FOR V101. Pfizer BioNTech 23DEC2020
	C4591001 1126 11261151	2	121	28JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Pfizer BioNTech Covid 19 Vaccine outside of study 27JAN2021
	C4591001 1127 11271022	1	62	29SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	after multiple TC attempts and certified letter and returned 11/10/2020 subject is lost to follow up
	C4591001 1127 11271078	2	137	11JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to followup
	C4591001 1127 11271099	1	22	09SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject tested positive and symptoms for COVID
	C4591001 1127 11271112	2	86	04DEC2020	FOLLOW-UP	DEATH	DEATH/CARDIO-RESPIRATORY ARREST

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1128 11281026	2	153	19JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	DROPPED-SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY
	C4591001 1128 11281055	2	65	29OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject contact attempted several times, certified letter sent, no response
		2	65	29OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	after several attempts and certified letter, subject has not responded
	C4591001 1128 11281083	2	113	22DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY
	C4591001 1128 11281086	2	43	13OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject wishes to discontinue from study
		2	43	13OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject wished to discontinue study
	C4591001 1128 11281112	2	129	08JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	DROPPED-SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY
	C4591001 1128 11281146	1	64	21OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject is lost to follow up
		1	64	21OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	AFTER SEVERAL ATTEMPTS TO CONTACT, CERTIFITED LETTER SENT 16SEP2020
	C4591001 1128 11281159	2	49	29OCT2020	VACCINATION	LOST TO FOLLOW-UP	after several attempts and certified letter sent, subject is lost to follow up
		2	49	29OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	after several attempts and certified letter sent, subject is lost to follow up

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1128 11281164	2	61	10NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT, GOT A NEW JOB AND CAN'T RETURN FOR VISITS
		2	61	10NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT, GOT A NEW JOB AND CAN'T RETURN FOR VISITS
	C4591001 1128 11281177	2	113	19JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY
	C4591001 1128 11281227	2	105	31DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	DROPPED-SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY
	C4591001 1128 11281265	2	114	15JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY
	C4591001 1128 11281279	2	48	09NOV2020	VACCINATION	LOST TO FOLLOW-UP	AFTER SEVERAL ATTEMPTS TO REACH SUBJECT, CERTIFIED LETTER WAS SENT WITH NO RESPONSE
		2	48	09NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	AFTER SEVERAL ATTEMPTS TO REACH SUBJECT, CERTIFIED LETTER WAS SENT WITH NO RESPONSE
	C4591001 1128 11281292	2	160	01MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	subject is lost to follow up
	C4591001 1128 11281368	1	46	31OCT2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT DID NOT RETURN TO CLINIC FOR V2. CERTIFIED LETTER SENT
		1	46	31OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT DID NOT RETURN TO CLINIC FOR V2. CERTIFIED LETTER SENT
	C4591001 1129 11291048			04AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	screen fail

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
				04AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	violation exclusion criteria 2.f. immunocompromised. randomized but not dosed
	C4591001 1129 11291064	2	118	23DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	subject received Covid-19 vaccine outside of trial
	C4591001 1129 11291072	2	111	19DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	subject received Covid-19 vaccine outside of trial
	C4591001 1129 11291088	2	52	22OCT2020	VACCINATION	OTHER	no longer LTFU
	C4591001 1129 11291089	2	52	22OCT2020	VACCINATION	OTHER	no longer LTFU
	C4591001 1129 11291249	1	124	24FEB2021	VACCINATION	WITHDRAWAL BY SUBJECT	Participant has relocated to another state and is not willing to return for follow up
		1	124	24FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal of consent, subject moved with no intention of transferring to other site.
	C4591001 1129 11291260	2	44	27JAN2021	OPEN LABEL TREATMENT	ADVERSE EVENT	ADVERSE EVENT/ANAPHYLACTOID REACTION
	C4591001 1131 11311024	1	39	24SEP2020	VACCINATION	LOST TO FOLLOW-UP	subject received vax1 (17AUG2020) but no showed for vax2. Now LTFU
		1	39	24SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Multiple attempts made after no-show for V2,no response.Certified letter sent. Signed 24SEP2020
	C4591001 1131 11311193	1	32	19OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject did not returned office calls for follow up
		1	32	19OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject did not returned office calls for follow up

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1133 11331016	2	179	18FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1133 11331023	2	36	25SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		2	36	25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331037	1	27	26AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
		1	27	26AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331042	1	21	20AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
		1	21	20AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1133 11331047	2	8	31AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject does not want to continue in the study
		2	8	31AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331052	1	10	12AUG2020	VACCINATION	LOST TO FOLLOW-UP	Certified Letter sent out Subject Lost to Follow up
		1	10	12AUG2020	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter was sent
	C4591001 1133 11331069	2	75	10NOV2020	VACCINATION	LOST TO FOLLOW-UP	Unable to contact subject

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		2	88	23NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Site sent certified letter on 10Nov2020
	C4591001 1133 11331087	1	7	14AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
		1	7	14AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1133 11331105	2	185	04MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1133 11331120	2	62	30NOV2020	VACCINATION	LOST TO FOLLOW-UP	Certified letter was sent.
		2	62	30NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject never answered the phone. Certified letter was sent
	C4591001 1133 11331122	1	20	31AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject was called because he was not complying with the diary. Subject withdrew consent
		1	20	31AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331129	2	151	01FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT NO LONGER INTERESTED IN PARTICIPATING IN STUDY
	C4591001 1133 11331130	2	158	08FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject states he received the vaccine already but did not provide any information
	C4591001 1133 11331135	2	166	16FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent after unblinding. Requested time to think about it. Made decision on 16/FEB
	C4591001 1133 11331138	1	24	04SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject stated she is not happy with the study number of visits, number of vaccines, payments.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	24	04SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject stated she is not happy with the study number of visits, number of vaccines, payments.
	C4591001 1133 11331158	2	176	26FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331162			14AUG2020	SCREENING	OTHER	DELAY CRITERIA MET
				05OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331170	1	67	19OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not answer to any attempts. A certified letter was sent.
		1	67	19OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent
	C4591001 1133 11331177	2	68	10NOV2020	VACCINATION	LOST TO FOLLOW-UP	Unable to contact subject
		2	81	23NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Site sent certified letter on 10Nov2020
	C4591001 1133 11331188	2	162	17FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent. Refused vaccination
	C4591001 1133 11331207	1	43	30SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
		1	43	30SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1133 11331209	2	171	26FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT 19/FEB/21

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1133 11331256	2	111	04JAN2021	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	Inclusion #2 - Not compliant with diary
	C4591001 1133 11331278	2	162	26FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT 19/FEB/2021
	C4591001 1133 11331291	1	47	12OCT2020	VACCINATION	LOST TO FOLLOW-UP	Certified letter sent on 12/OCT/2020
		1	47	12OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent on 12/OCT/2020
	C4591001 1133 11331294	2	51	07NOV2020	VACCINATION	LOST TO FOLLOW-UP	Site sent certified letter on 03Nov2020. Received by subject on 07Nov2020
		2	51	07NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Site sent certified letter on 3Nov2020. Subject received on 7/NOV/20
	C4591001 1133 11331295	1	44	09OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
		1	44	09OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331338	1	50	17OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		1	50	17OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1133 11331340	2	155	26FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT 19/FEB/2021
	C4591001 1133 11331341	1	45	12OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject is LTF. Certified letter sent 12/OCT/20

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	45	12OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT IS LTF. CERTIFIED LETTER SENT 12/OCT/20
	C4591001 1133 11331348	2	51	10NOV2020	VACCINATION	LOST TO FOLLOW-UP	Site sent certified letter on 10Nov2020
		2	51	10NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Site sent certified letter on 10Nov2020
	C4591001 1133 11331354	2	62	23NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331357	2	148	17FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1133 11331378	2	157	26FEB2021	FOLLOW-UP	OTHER	Subject was dropped due to non-compliance with study visits.
	C4591001 1133 11331388	2	169	12MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent 26/FEB/2021
	C4591001 1133 11331414	2	157	05MAR2021	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1133 11331418	2	150	26FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent 19/FEB/21
	C4591001 1133 11331438	2	114	21JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECEIVED COVID-19 VACCINE AT WORK
	C4591001 1133 11331441	2	111	18JAN2021	VACCINATION	OTHER	Subject in Japan. Not compliant with visits.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		2	111	18JAN2021	FOLLOW-UP	OTHER	Subject is in Japan. He is not able to compliant with visits.
	C4591001 1133 11331450	2	53	30NOV2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
		2	53	30NOV2020	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1133 11331480	2	127	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT 08/FEB/2021
		2	136	26FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	certified letter sent 19/FEB
	C4591001 1133 11331483	2	136	26FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	certified letter sent 19/FEB
	C4591001 1133 11331490	2	29	11NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		2	29	11NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew consent. No longer interested in coming for Follow-up visits
	C4591001 1133 11331492	2	29	11NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		2	29	11NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew consent. No longer interested in coming for Follow-up visits
	C4591001 1133 11331499	2	17	30OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject does not wish to continue with study,he asked us to please do notcall him again.
		2	17	30OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject does not want to be contacted anymore
	C4591001 1133 11331509	1	26	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	Unable to contact subject

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	26	20OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Unable to contact subject
	C4591001 1133 11331510	1	20	14OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject doesn't feels comfortable receiving the second vaccine.
		1	20	14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT DOES NOT FEEL COMFORTABLE RECEIVING 2ND VACCINE. Subject wishies to no longer be contacted.
	C4591001 1133 11331512	1	26	20OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Meets exclusion 5
	C4591001 1133 11331553	2	78	01FEB2021	VACCINATION	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT 22/JAN/2021
		2	78	01FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT 22/JAN/2021
	C4591001 1133 11331555	2	36	21DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received COVID-19 vaccine at Hospital
	C4591001 1133 11331557	2	87	10FEB2021	VACCINATION	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT
		2	87	10FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT
	C4591001 1133 11331561	2	95	18FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1133 11331562	1	20	14NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	EXCLUSION CRITERIA 5
	C4591001 1133 11331568	1	24	18NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	24	18NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wants to be contacted.
	C4591001 1133 11331583	1	68	04JAN2021	VACCINATION	LOST TO FOLLOW-UP	Certified letter sent 15/DEC/2020
		1	68	04JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT 15/DEC/2020
	C4591001 1133 11331594	2	84	10FEB2021	VACCINATION	LOST TO FOLLOW-UP	Certified letter 17/DEC/20
		2	84	10FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT 17/DEC/20
	C4591001 1133 11331598	1	68	04JAN2021	VACCINATION	LOST TO FOLLOW-UP	Certified letter sent 15/DEC/2020
		1	68	04JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent 15/DEC/2020
	C4591001 1133 11331635	1	67	04JAN2021	VACCINATION	LOST TO FOLLOW-UP	Certified letter sent 15/DEC/2020
		1	67	04JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent 15/DEC/2020
	C4591001 1133 11331644	2	76	02FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
		2	76	02FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331647	2	31	23DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject leaving and does not want to come in for any future visits.
	C4591001 1134 11341033	1	35	14SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Dropped

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	35	14SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1134 11341153	1	2	25AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/EYE PAIN
	C4591001 1134 11341174	1	5	30AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/HEADACHE
	C4591001 1134 11341210	2	1	18SEP2020	VACCINATION	LOST TO FOLLOW-UP	subject is lost to follow up
		2	1	18SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject has been called 08OCT2020-23OCT2020 with no response. A certified letter was sent on Nov30.
	C4591001 1135 11351029	2	131	04JAN2021	FOLLOW-UP	OTHER	subject moved out of state
	C4591001 1135 11351061	1	57	02OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent
		1	57	02OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1135 11351132	2	38	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject contact attempted several times, certified letter mailed on 08OCT2020.
		2	38	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject lost to follow-up
	C4591001 1135 11351199	1	39	01OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up, certified letter sent to patient.
		1	39	01OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject lost to follow-up, certified letter sent

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1135 11351200	1	54	16OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up, certified letter sent to patient.
		1	54	16OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject lost to follow-up, certified letter was sent
	C4591001 1135 11351212	1	35	28SEP2020	VACCINATION	LOST TO FOLLOW-UP	patient was lost to follow up. certified letter was sent.
		1	35	28SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject lost to follow-up, certified letter was sent
	C4591001 1135 11351241	2	148	16FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	subject dropped due to receiving Moderna vaccine
	C4591001 1135 11351389			19SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	during screening visit, subject withdrew consent after randomization
	C4591001 1135 11351420	1	27	19OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject contact attempted several times and certified letter sent 19OCT2020
		1	27	19OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject contact attempted several times and certified letter sent on 19OCT2020
	C4591001 1135 11351428	1	27	19OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject contact attempted several times and certified letter was sent on 19OCT2020
		1	27	19OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject contact attempted several times and certified letter was sent on 19OCT2020
	C4591001 1135 11351430	1	26	19OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject contact attempted several times and certified letter sent on 19OCT2020
		1	26	19OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject contact attempted several times and certified letter sent on 19OCT2020

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1135 11351436	2	37	20NOV2020	VACCINATION	LOST TO FOLLOW-UP	subject LTFU, certified letter was mailed
		2	37	20NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject LTFU, certified letter was mailed
	C4591001 1135 11351523	1	18	10NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent
		1	18	10NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1135 11351555	2	61	16JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	subject dropped from trial
	C4591001 1135 11351564	2	1	17NOV2020	VACCINATION	OTHER	subject moved out of state, EOT updated with V2 visit DOV
	C4591001 1136 11361043	1	89	20NOV2020	VACCINATION	LOST TO FOLLOW-UP	Certified letter returned unclaimed
		1	89	20NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject unable to be contacted.
	C4591001 1136 11361045	1	75	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Unable to contact subject after multiple attempts and certified letter sent
		1	75	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Unable to contact subject after multiple attempts and certified letter.
	C4591001 1139 11391042	2	156	29JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject decided to receive vaccine elsewhere after being unblinded.
	C4591001 1139 11391109	2	44	18DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject decided to get vaccine at place of employment after being unblinded

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1140 11401176	2	135	23JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Moderna Vaccine outside of the clinical trial. Withdrawn from the study.
	C4591001 1140 11401177	2	155	12FEB2021	VACCINATION	PROTOCOL DEVIATION	Missed Visit 3 as contact with subject could not be made and could not return to clinic in time.
	C4591001 1140 11401301	1	86	12JAN2021	VACCINATION	WITHDRAWAL BY SUBJECT	Contact was made on 12Jan2021 after multiple attempts. Subject confirmed to withdraw consent.
		1	86	12JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject states that he no longer would like to participate in trial.
	C4591001 1140 11401306	1	23	13NOV2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/AMNESIA
		1	125	23FEB2021	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/PARAPARESIS
		1	125	23FEB2021	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/VISUAL IMPAIRMENT
	C4591001 1141 11411027	2	106	17DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Participant withdrew to receive EUA vaccine outside of the study.
	C4591001 1141 11411077	2	118	04JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew to receive EUA vaccine outside of the study.
	C4591001 1141 11411193	2	82	21DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew to receive EUA vaccine outside of the study.
	C4591001 1142 11421084	2	62	04NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Discontinued d/t medical history discovered after enrollment per instructions of CRA
		2	62	04NOV2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	Discontinued d/t medical history discovered after enrollment per instructions of CRA

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1142 11421112	2	147	01FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Moderna vaccine.
	C4591001 1142 11421141	2	111	30DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Discontinued
	C4591001 1142 11421303	2	1	12NOV2020	VACCINATION	OTHER	Subject left on an extended trip out of state and is not sure if/when he will return
	C4591001 1145 11451037	2	121	13JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal of consent
	C4591001 1146 11461140	2	178	13MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew
	C4591001 1146 11461195	2	173	13MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal by subject
	C4591001 1146 11461240	2	88	01JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Discontinued
	C4591001 1147 11471001	2	173	09FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Non-study COVID-19 Vaccine
	C4591001 1147 11471047	2	178	19FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Non-study COVID-19 Vaccine (Moderna)
	C4591001 1147 11471212	1	21	23SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	21	23SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1149 11491005	1	21	25AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	patient will be out of state for a long period of time so unable to return for study visits
		1	21	25AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	pt withdrew consent from study. unable to return for visits due to upcoming scheduling conflicts
	C4591001 1149 11491007	2	18	11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent and no longer wishes to continue in study citing personal reasons
		2	18	11SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent and no longer wishes to participate in the study due to personal reasons
	C4591001 1149 11491031	1	68	16OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up left several VM and certified letter send 09oct2020.
		1	68	16OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	patient has been unresponsive to repeated site contacts via phone, email and certified letter
	C4591001 1149 11491040	2	169	16FEB2021	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject took non-study covid vaccine.
	C4591001 1149 11491065	1	31	11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	pt is withdrawing consent from study due to personal reasons
		1	31	11SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent and does not wish to continue in study citing personal reasons
	C4591001 1149 11491067	1	21	01SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	patient withdrew consent from the study
		1	21	01SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent and no longer wishes to participate in the study

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1149 11491108			20AUG2020	VACCINATION	REFUSED FURTHER STUDY PROCEDURES	REFUSED FURTHER STUDY PROCEDURES
				20AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent right before vaccination
	C4591001 1149 11491230	1	60	09NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject sent LTFU certified letter 30OCT2020.
		1	60	09NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is non responsive. Certified letter sent 30OCT2020.
	C4591001 1149 11491285	2	50	03DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject didn't want to participate in study and wished to withdraw.
	C4591001 1149 11491332	2	23	03DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject moved out of State and will not be able to committee to follow-ups
		2	23	03DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject moved out of state and withdrew from study.
	C4591001 1149 11491344†	1	39	04DEC2020	VACCINATION	LOST TO FOLLOW-UP	No response from patient following visit 1. LTFU certified letter was sent on 04-Dec-2020.
		1	39	04DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	No response from subject following visit 1. LTFU certified letter was sent 04-Dec-2020.
	C4591001 1152 11521030	1	22	02SEP2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1152 11521034	1	41	21SEP2020	VACCINATION	LOST TO FOLLOW-UP	Several phone messages were left for subject. Certified letter was sent.
		1	41	21SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent; return receipt received back signed by someone other than the subject.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1152 11521043	2	10	10SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Now has 2 jobs and has no time to do study.
		2	10	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrawal by subject due to time constraints.
	C4591001 1152 11521077	2	1	03SEP2020	VACCINATION	OTHER	Subject had both vaccinations and then moved out of state. No Visit 3 was or ever will be done.
		2	33	05OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT MOVED TO ARIZONA
	C4591001 1152 11521085	1	8	26AUG2020	VACCINATION	DEATH	DEATH/DEATH
		1	8	26AUG2020	FOLLOW-UP	DEATH	DEATH/DEATH
	C4591001 1152 11521137	2	103	22DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Received alternative COVID-19 Vaccine, withdrawn from study.
	C4591001 1152 11521138	2	78	04DEC2020	VACCINATION	PROTOCOL DEVIATION	Non-compliant with attending study visits.
		2	78	04DEC2020	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1152 11521192	2	180	12MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Received alternative COVID-19 Vaccine, withdrawn from study.
	C4591001 1152 11521208	2	81	04DEC2020	VACCINATION	PROTOCOL DEVIATION	Non-compliant with attending study visits.
		2	115	07JAN2021	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1152 11521394	2	64	30NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	MOVED TO TEXAS.
		2	64	30NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	MOVED TO TEXAS.
	C4591001 1156 11561006	1	20	08SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criteria 5
	C4591001 1156 11561015	1	39	28SEP2020	VACCINATION	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY
	C4591001 1156 11561033	1	16	10SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criteria 5
	C4591001 1156 11561124	2	32	02NOV2020	VACCINATION	DEATH	DEATH/RESPIRATORY ARREST
		2	32	02NOV2020	FOLLOW-UP	DEATH	DEATH/OVERDOSE
	C4591001 1157 11571003	1	56	06OCT2020	VACCINATION	LOST TO FOLLOW-UP	All attempts to contact subject have not been successful.
		1	56	06OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	All attempts to contact subject have been unsuccessful
	C4591001 1157 11571070	1	38	01OCT2020	VACCINATION	LOST TO FOLLOW-UP	All attempts to contact subject have been unsuccessful
		1	38	01OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	All attempts to contact subject have been unsuccessful
	C4591001 1157 11571077	2	30	14OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject W/C due to moving

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		2	30	14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Voluntary withdrawal not due to an AE or SAE
	C4591001 1157 11571090	2	162	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Multiple attempts to contact subject for Revax, certified letter sent. No response
	C4591001 1157 11571092	2	136	28JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	voluntary withdrawal not due to an AE or SAE
	C4591001 1157 11571109	2	94	17DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject could not wait to receive vaccine at the site level
	C4591001 1157 11571118	2	87	17DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent due to imminent receipt of Pfizer vaccine at an outside facility
	C4591001 1157 11571121	2	169	08MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts to contact regarding scheduling for V101. Certified letters sent. No response.
	C4591001 1157 11571135	1	23	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Voluntary withdrawal not due to an adverse event
		1	156	04FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Voluntary withdrawal not due to an AE or SAE
	C4591001 1157 11571174	2	104	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts to contact subject for vaccination. Certified letter sent. No response
	C4591001 1161 11611002	1	85	23OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion 5
		1	218	05MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	3 unsuccessful contacts and a certified letter sent and returned.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1161 11611005	1	127	04DEC2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
		1	183	29JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1161 11611006	1	111	18NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject chose to withdraw from study
		1	111	18NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject chose to withdraw from study.
	C4591001 1161 11611007	1	103	10NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	No longer meets an eligibility criteria per exclusion #5. VAX2 is not given but FUP will be complete
		1	146	23DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	unable to contact, certified letter was sent and no response.
	C4591001 1161 11611008	1	103	10NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1161 11611010	1	134	11DEC2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
		1	216	03MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject stated he did not want to continue in study.
	C4591001 1161 11611018	1	115	23NOV2020	VACCINATION	LOST TO FOLLOW-UP	multiple calls and cert. letter sent. No response from subject.
		1	115	23NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	multiple calls and certified letter sent. no response from subject
	C4591001 1161 11611020	2	99	01MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	unable to contact 3 phone calls and cert. letter sent on 08FEB2021

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1161 11611023	1	72	13OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject had several contact attempts by site along with certified letter. Unable to contact subject.
		1	72	13OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	cert. letter sent and signed by subject. unable to contact and subject has not called site.
	C4591001 1161 11611024	1	107	17NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	unable to contact subject. certified letter returned, no response from subject
		1	107	17NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject did not want to continue in study
	C4591001 1161 11611028	2	83	02FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	3 phone call attempts and certified letter sent with no response.
	C4591001 1162 11621005	1	32	31AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject prematurely withdrew from study.
		1	32	31AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject prematurely withdrawn from study.
	C4591001 1162 11621024			06AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Randomized in error
	C4591001 1162 11621044	2	194	09MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow-up
	C4591001 1162 11621074	2	73	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	subject LTFU after multiple contact attempts.
		2	73	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject LTFU after multiple contact attempts.
	C4591001 1162 11621080	2	64	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		2	64	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU
	C4591001 1162 11621118	1	35	16SEP2020	VACCINATION	LOST TO FOLLOW-UP	SUBECT WITHDREW,CERTIFIED LETTER SENT 9/16/2020
		1	35	16SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject withdrew from study
	C4591001 1162 11621137	2	66	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU after multiple contact attempts.
		2	66	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU after multiple contact attempts.
	C4591001 1162 11621164	2	66	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	subject LTFU after multiple contact attempts.
		2	66	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU after multiple contact attempts.
	C4591001 1162 11621168	2	54	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
		2	54	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
	C4591001 1162 11621224	2	70	29NOV2020	VACCINATION	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
		2	70	29NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
	C4591001 1162 11621254	2	30	21OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Early termination by subject after visit 2 due to work schedule
		2	30	21OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Early termination by subject after visit 2 due to work schedule
	C4591001 1162 11621294	1	60	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU after many contact attempts
		1	60	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU after many contact attempts

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1162 11621308	2	1	29SEP2020	VACCINATION	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
		2	1	29SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
	C4591001 1162 11621310	1	60	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU
		1	60	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU
	C4591001 1162 11621336	2	31	30OCT2020	VACCINATION	OTHER	Subject was initially Lost to Follow-up but rejoined the study to receive vaccination 3
	C4591001 1162 11621356	1	61	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	subject LTFU; did not return to site
		1	61	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject lost to follow up
	C4591001 1162 11621374	1	54	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU
		1	54	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU after many contact attempts.
	C4591001 1162 11621381	1	54	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject lost to follow up
		1	54	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject lost to follow up
	C4591001 1162 11621391	1	51	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject Lost to Follow Up after many attempts to contact.
		1	51	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject Lost to Follow Up after many attempts to contact.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1162 11621393	2	1	09OCT2020	VACCINATION	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
		2	1	09OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
	C4591001 1162 11621434	2	1	19OCT2020	VACCINATION	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
		2	1	19OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
	C4591001 1162 11621477			30SEP2020	FOLLOW-UP	PROTOCOL DEVIATION	Randomized in error
	C4591001 1162 11621480	2	32	28NOV2020	VACCINATION	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
		2	32	28NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
	C4591001 1162 11621514	1	1	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent
		1	1	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1162 11621515	1	1	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent
		1	1	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1162 11621524	1	30	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	subject LTFU
		1	30	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject Lost to follow-up

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1162 11621540	2	31	11DEC2020	VACCINATION	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
		2	31	11DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
	C4591001 1162 11621566	1	34	24NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU, certified letter sent
		1	34	24NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	LTFU- letter mailed to subject
	C4591001 1163 11631006	1	21	20AUG2020	VACCINATION	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT/PRODUCT ADMINISTRATION ERROR
	C4591001 1163 11631059	1	2	08AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DRUG HYPERSENSITIVITY
	C4591001 1163 11631123	2	58	04NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
		2	58	04NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1166 11661037	2	37	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject refused further procedures.
		2	37	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient refused further study procedures. Updated per DM.
	C4591001 1166 11661044	2	99	28DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	PT W/D CONSENT DURING V101 (VAX3). AFTER ALL PROCEDURES BUT IMMEDIATELY BEFORE VACCINE.
		2	99	28DEC2020	REPEAT SCREENING 1	OTHER	PATIENT WITHDREW CONSENT IMMEDIATELY PRIOR TO VACCINATION.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1166 11661047	1	1	31AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DIZZINESS
	C4591001 1166 11661051	2	92	22DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	PT WITHDREW AFTER CONSENTING TO VAX3 ONLY AFTER PROCEDURES, IMMEDIATELY PRIOR TO VAX3 ITSELF.
		2	92	22DEC2020	REPEAT SCREENING 1	OTHER	WOC
	C4591001 1167 11671003			14AUG2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	Did not meet inclusion criteria #3
	C4591001 1167 11671071	2	113	04JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Received COVID vaccine outside the study
	C4591001 1167 11671111	1	38	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject is lost to follow up tried multiple calls and certified letter
		1	38	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	no answer after multiple calls and sent certified letter
	C4591001 1167 11671132	2	98	28DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	subject received out of study covid vaccine
	C4591001 1168 11681030			15AUG2020	VACCINATION	PROTOCOL DEVIATION	randomized in error
				15AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	subject randomized in error
	C4591001 1168 11681032	2	128	14JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent to receive vaccine at work
	C4591001 1168 11681039	2	106	22DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal by subject

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1168 11681070	2	29	02NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Pt. will no longer complete study visits due to her schedule and withdrew consent to participate
		2	29	02NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt would not return for visits as required and chose to no longer participate Verbal WOC
	C4591001 1168 11681077	2	28	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	PATIENT WITHDREW CONSENT
		2	28	12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient withdrew consent
	C4591001 1168 11681094	2	117	11JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal by subject
	C4591001 1168 11681097	2	1	15SEP2020	VACCINATION	OTHER	The subject is unable to complete V3 due to his work. Pt will complete the rest of the study visits
	C4591001 1168 11681104	1	70	05NOV2020	VACCINATION	LOST TO FOLLOW-UP	multiple attempts to reach patient for missed Visit 2 and no response.
		1	70	05NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts to reach patient after missed Visit 2 and no response.
	C4591001 1168 11681116	2	101	30DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt chose to longer complete any study procedures
	C4591001 1168 11681178	2	34	10NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	The patient chose to no longer participate due to distance and an assumption of placebo group
		2	34	10NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the subject withdrew consent to participate

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1168 11681212	2	1	15OCT2020	VACCINATION	OTHER	The visit was missed due to pt working out of state. The subject will continue on in the study.
	C4591001 1168 11681221	2	54	21DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject chose to no longer participate, complete study procedures, or respond to follow up requests.
		2	54	21DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject chose to no longer participate, complete study procedures, or respond to follow up requests.
	C4591001 1168 11681227	1	37	17NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTF after several attempts to contact and certified letter sent
		1	37	17NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTF after several attempts to contact and certified letter sent
	C4591001 1169 11691014	2	104	04JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject did not want to wait 28 days to receive study vaccine after receiving HPV vaccine 12/21/20
	C4591001 1169 11691023	2	93	30DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received covid vaccine outside of the study - withdrawn
	C4591001 1169 11691034	2	113	20JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject withdrew consent, received Covid Vaccine outside of Study
	C4591001 1169 11691057	2	84	30DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received covid vaccine outside of the study, prior to unblinding- withdrawn from study
	C4591001 1169 11691058	1	17	02OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Covid +
	C4591001 1169 11691060	2	36	17NOV2020	VACCINATION	LOST TO FOLLOW-UP	Lost to Follow Up

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		2	36	17NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1169 11691069	2	85	30DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received a covid vaccine outside of the study prior to unblinding- withdrawn
	C4591001 1170 11701013	2	119	04JAN2021	FOLLOW-UP	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY
	C4591001 1170 11701026	2	101	17DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received vaccine outside of study.
	C4591001 1170 11701045	2	127	14JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received vax outside of study
	C4591001 1170 11701048	2	166	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1170 11701076	2	163	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1170 11701077	2	163	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1170 11701081	2	99	22DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject vaccinated outside the study.
	C4591001 1170 11701089	2	161	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1170 11701110	2	96	21DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received vaccine outside of study.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1170 11701146	2	168	09MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up subject contacted multiple times for scheduling
	C4591001 1170 11701171	2	112	12JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Received vaccine outside of study
	C4591001 1170 11701209	2	141	12FEB2021	OPEN LABEL TREATMENT	PROTOCOL DEVIATION	subject got his second vaccine outside the trial
		2	141	12FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject got his second vaccine outside the trial
	C4591001 1170 11701231	2	84	21DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	received vaccine outside of study before withdrawing consent
	C4591001 1170 11701296	2	91	31DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	received vaccine elsewhere while in study
	C4591001 1170 11701311	1	33	16OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject contacted multiple times, never responded.
		1	33	16OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow-up subjects subject didnt come for visit.
	C4591001 1170 11701359	2	92	11JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up subject contacted a couple times and subject didnt contact the site
	C4591001 1170 11701393	2	78	27JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject decided to get vaccine through employer
	C4591001 1170 11701413	2	38	18DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received vaccine outside the study.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1170 11701427†	1	51	11DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject has multiple times rescheduled. Last time did not contact and was a no show
		1	59	19DEC2020	VACCINATION	LOST TO FOLLOW-UP	Subject has multiple times rescheduled. Last time did not contact and was a no show
	C4591001 1170 11701487	2	99	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1170 11701494	2	99	23FEB2021	VACCINATION	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
		2	99	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1171 11711004	2	29	28SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject stated they do not want to participate in the study anymore. Subject withdrew consent.
		2	29	28SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject stated they do not want to participate in the study anymore. Subject withdrew consent.
	C4591001 1171 11711023	2	189	09MAR2021	OPEN LABEL TREATMENT	ADVERSE EVENT	ADVERSE EVENT/ANGIOEDEMA
		2	189	09MAR2021	OPEN LABEL TREATMENT	ADVERSE EVENT	ADVERSE EVENT/URTICARIA
	C4591001 1171 11711042	1	39	24SEP2020	VACCINATION	LOST TO FOLLOW-UP	Per PI instructions subject LTFU
		1	39	24SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Per PI instructions subject LTFU
	C4591001 1171 11711046	2	171	25FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject was unblinded and is not interested in continuing with the study

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1171 11711071	2	178	12MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received MRNA 1273 outside of study
	C4591001 1171 11711072	1	37	24SEP2020	VACCINATION	LOST TO FOLLOW-UP	Per PI instructions subject is LTFU
	C4591001 1171 11711077	2	184	12MAR2021	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject moved and will no longer be able to continue with the study
	C4591001 1171 11711131	1	45	09OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU.
	C4591001 1171 11711159	1	39	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	Per PI instructions, subject LTFU.
	C4591001 1171 11711181	2	171	12MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received MRNA 1273 outside of the study
	C4591001 1171 11711183	2	171	12MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received MRNA 1273 outside of the study
	C4591001 1171 11711186	2	171	12MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received MRNA 1273 outside of the study
	C4591001 1171 11711247	2	165	12MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received MRNA 1273 outside of study

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1171 11711250	2	165	12MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received a covid-19 vaccine outside of the study
	C4591001 1171 11711256	2	158	12MAR2021	OPEN LABEL TREATMENT	WITHDRAWAL BY SUBJECT	Subject will proceed with v102VAX4 but has decided to continue without receiving the vaccine
	C4591001 1171 11711261	2	158	12MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received COVID-19 vaccine outside of study without informing site - MRNA 1273
	C4591001 1171 11711301	1	62	30NOV2020	VACCINATION	LOST TO FOLLOW-UP	Per PI, subject LTFU
		1	62	30NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Multiple attempts to reschedule subject made, Per PI's instructions, this subject is considered LTFU
	C4591001 1177 11771139	1	74	06NOV2020	VACCINATION	OTHER	Subject was initially lost to follow up but then rejoined the trial at a later date
	C4591001 1177 11771332	2	144	22FEB2021	FOLLOW-UP	OTHER	Subject moved out of state and will no longer be able to complete study visits
	C4591001 1177 11771369	2	126	09FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received a non study COVID-19 vaccination outside of the study
	C4591001 1177 11771449	2	84	05JAN2021	OPEN LABEL TREATMENT	WITHDRAWAL BY SUBJECT	Subject withdrew consent on 05 Jan 2021
		2	84	05JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent on 05 Jan 2021
	C4591001 1178 11781065	2	120	18JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Received Moderna vaccine outside study.

16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1178 11781107	1	22	25SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/LYMPHADENOPATHY
	C4591001 1179 11791115	2	106	08FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject chose to receive vaccine out of study upon learning they received placebo initially.
	C4591001 1179 11791138	1	11	03NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5. VAX2 is not given but FUP will be completed.
	C4591001 1185 11851055	2	90	16FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrawal informed consent
	C4591001 1194 11941088	2	41	22DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Possibility of regular vaccination was given
	C4591001 1195 11951029	2	78	20JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the upcoming visits is to stressful for the patient at this time.
	C4591001 1195 11951061	1	21	06NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	patient withdrawal consent. she is afraid about the second vaccination
		1	21	06NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient is afraid for the second vaccination
	C4591001 1204 12041094	2	95	04JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Participant was vaccinated outside study with Pfizer vaccine.
	C4591001 1204 12041197†	1	37	13NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Participant has chosen to withdraw from the study.
		1	37	13NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1204 12041280	2	116	08MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Received COVID vaccine outside of study
	C4591001 1205 12051028			30OCT2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/BLOOD PRESSURE INCREASED
	C4591001 1205 12051078	1	9	18NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Volunteer was diagnosed with Covid-19 illness on 18Nov2020 then VAX2 can not be performed.
	C4591001 1207 12071045	2	64	26JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Covid-19 vaccine outside the study
		2	64	26JAN2021	REPEAT SCREENING 1	NO LONGER MEETS ELIGIBILITY CRITERIA	RECEIVED CORONAVAC OUTSIDE THE STUDY
	C4591001 1208 12081012	2	63	18JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	She voluntarily withdrew her consent because she had received a non-study vaccine.
	C4591001 1209 12091013	1	9	10NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5. VAX2 won't given but follow-up will be completed.
		1	57	28DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject did not withdraw his consent from the study.
	C4591001 1210 12101019	1	17	12NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject is diagnosed with symptomatic COVID19.
	C4591001 1210 12101053	1	18	22NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject is diagnosed with symptomatic COVID-19
	C4591001 1212 12121023			03NOV2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	After PI judgement, subject was not vaccinated.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1212 12121035	2	30	25DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject didn't want to continue to study, withdrawn his consent.
	C4591001 1213 12131002	2	75	26JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawl cosent for no any further contact with subject
	C4591001 1213 12131038	2	107	10MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawl consent for no any further contact with subject
	C4591001 1213 12131046	1	39	14DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrawl consent for no any further contact With subject
		1	39	14DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawl consent for no any further contact With subject
	C4591001 1217 12171031	1	39	07DEC2020	VACCINATION	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY
	C4591001 1217 12171044	1	7	10NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
		1	121	04MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	He withdrew from the study because he give up vaccinated.
	C4591001 1218 12181011	2	99	02MAR2021	VACCINATION	WITHDRAWAL BY SUBJECT	We made contact with participant 02MAR2021, she was informed of her vaccine status but withdrew.
		2	99	02MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Participant requested to withdraw from study as they have moved out of state
	C4591001 1218 12181018	2	26	29DEC2020	VACCINATION	OTHER	Subject proceeded to open label prior to V3 in the blinded Rx phase.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1218 12181026	2	85	01MAR2021	VACCINATION	LOST TO FOLLOW-UP	Participant has missed 4 scheduled VAX 3 visits and will not answer nor return our phone calls.
		2	85	01MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Participant has missed 4 scheduled VAX 3 visits and will not answer nor return our phone calls.
	C4591001 1218 12181027	2	22	29DEC2020	VACCINATION	OTHER	Subject proceeded to open label prior to V3 in the blinded Rx phase.
	C4591001 1218 12181036	2	5	18DEC2020	VACCINATION	OTHER	Subject proceeded to open label prior to V3 in the blinded Rx phase.
	C4591001 1218 12181041	1	22	22DEC2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criterion 5
	C4591001 1218 12181042	1	21	21DEC2020	VACCINATION	OTHER	unblinded at this time for VAX3
	C4591001 1218 12181044	2	7	28DEC2020	VACCINATION	OTHER	Subject proceeded to open label prior to V3 in the blinded Rx phase.
	C4591001 1218 12181048	1	20	22DEC2020	VACCINATION	OTHER	Subject proceeded to open label prior to Vax2 in blinded treatment phase
	C4591001 1218 12181050	1	21	23DEC2020	VACCINATION	OTHER	Subject proceeded to open label prior to Vax2 in blinded treatment phase
	C4591001 1218 12181052	1	21	23DEC2020	VACCINATION	OTHER	Subject proceeded to open label prior to Vax2 in blinded treatment phase

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1218 12181057	1	46	22JAN2021	VACCINATION	OTHER	VAX 2 delayed due to SAE hospitalization. Then unblinded and received placebo, moved to VAX 3
	C4591001 1219 12191024	2	77	25JAN2021	OPEN LABEL TREATMENT	LOST TO FOLLOW-UP	participant out of country doing medical service unable to contact or emergency contact
	C4591001 1219 12191035	2	17	18DEC2020	VACCINATION	OTHER	subject proceeded to open label prior to visit 3
	C4591001 1219 12191048	2	22	06JAN2021	VACCINATION	OTHER	subject proceeded to open label prior to visit 3
	C4591001 1219 12191050	2	23	12JAN2021	VACCINATION	OTHER	subject proceeded to open label prior to visit 3
	C4591001 1219 12191053	2	25	15JAN2021	VACCINATION	OTHER	subject proceeded to open label prior to visit 3
	C4591001 1219 12191056	1	20	22DEC2020	VACCINATION	OTHER	subject proceeded to open label prior to Vax 2 in the blinded treatment phase
	C4591001 1219 12191062	1	11	18DEC2020	VACCINATION	OTHER	subject proceeded to open label prior to vax 2 in the blinded treatment phase
	C4591001 1220 12201029	2	58	14JAN2021	OPEN LABEL TREATMENT	WITHDRAWAL BY SUBJECT	Participant did not want to wait 28 days from oral steroid use to receive vax 4.
		2	58	14JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt. wanted to get second vaccine from employer. Pt. not willing to continue in study activities.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1220 12201032	2	25	17DEC2020	VACCINATION	OTHER	Participant was unblinded for emergency use authorization of COVID vaccine for healthcare workers.
	C4591001 1220 12201036	1	44	17DEC2020	VACCINATION	LOST TO FOLLOW-UP	unable to contact participant due to multiple attempts
	C4591001 1220 12201041	1	44	17DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	Unable to contact participant after multiple attempts
	C4591001 1220 12201041	2	18	17DEC2020	VACCINATION	OTHER	Participant was unblinded for EUA of the COVID vaccine for healthcare workers.
	C4591001 1220 12201051	2	7	17DEC2020	VACCINATION	OTHER	Participant was unblinded for EUA of COVID vaccine for healthcare workers.
	C4591001 1220 12201053	2	13	21DEC2020	VACCINATION	OTHER	Participant was unblinded for EUA of COVID vaccine for healthcare workers.
	C4591001 1220 12201056	2	6	16DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	Received COVID-19 vaccine at outside facility
	C4591001 1220 12201061	2	6	16DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent to receive vaccine from outside facility
	C4591001 1220 12201061	2	3	17DEC2020	VACCINATION	OTHER	Participant was unblinded for EUA of COVID vaccine for healthcare workers.
	C4591001 1220 12201065	1	37	07JAN2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Diagnosis of coronavirus with COVID illness symptoms
	C4591001 1221 12211007	2	11	17DEC2020	VACCINATION	OTHER	Cross over to V101

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1221 12211023	2	25	17DEC2020	VACCINATION	OTHER	Cross over to V101
	C4591001 1221 12211026	2	24	17DEC2020	VACCINATION	OTHER	Cross over to V101
	C4591001 1221 12211031	2	26	28DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	Participant request
		2	26	28DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew from study
	C4591001 1221 12211032	2	16	18DEC2020	VACCINATION	OTHER	Cross over to V101
	C4591001 1221 12211036	2	52	27JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew from study
	C4591001 1221 12211043	2	11	17DEC2020	VACCINATION	OTHER	Cross over to V101
	C4591001 1221 12211053	2	8	17DEC2020	VACCINATION	OTHER	Cross over to V101
	C4591001 1221 12211055	2	26	08JAN2021	VACCINATION	OTHER	Cross over to V101
	C4591001 1221 12211065	2	23	05JAN2021	VACCINATION	OTHER	Cross over to V101

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1221 12211072	2	1	21DEC2020	VACCINATION	OTHER	Cross over to V101
	C4591001 1221 12211078	1	22	23DEC2020	VACCINATION	OTHER	Cross over to V101 prior to V2
	C4591001 1221 12211081	2	18	08JAN2021	VACCINATION	OTHER	Cross over to V101
	C4591001 1221 12211089	2	15	11JAN2021	VACCINATION	OTHER	Cross over to V101
	C4591001 1221 12211090	2	17	04FEB2021	VACCINATION	OTHER	Not done due to crossover to V101
	C4591001 1223 12231054	2	148	16FEB2021	VACCINATION	OTHER	subject has been difficult to reach. did not show for visit 3 or 101. continuing efforts to reach.
	C4591001 1223 12231174	1	176	09MAR2021	VACCINATION	LOST TO FOLLOW-UP	subject cannot be reached. He is now considered lost to follow up.
		1	176	09MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject has missed visits and does not have a telephone. He is lost to followup.
	C4591001 1223 12231177	2	156	09MAR2021	VACCINATION	LOST TO FOLLOW-UP	subject cannot be reached. he is now considered lost to follow up.
		2	156	09MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	subject cannot be reached. he is now considered lost to follow up.
	C4591001 1223 12231200			21SEP2020	FOLLOW-UP	PROTOCOL DEVIATION	subject randomized in error

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1223 12231219	2	138	09MAR2021	VACCINATION	OTHER	visit 3 window has passed but still trying to reach subject.
	C4591001 1223 12231234			12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject left the site before vaccination 1
	C4591001 1224 12241009	1	37	18SEP2020	VACCINATION	LOST TO FOLLOW-UP	PT failed to attend V2; site attempted contact via phone and certified letter
		1	37	18SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	PT failed to return for V2; site attempted contact via phone and certified letter
	C4591001 1224 12241065	1	13	05SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/HEART RATE IRREGULAR
	C4591001 1224 12241167	1	27	16DEC2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criteria 5
	C4591001 1224 12241169	2	23	06JAN2021	VACCINATION	OTHER	subject proceeded to open label prior to V3 in the blinded Rx phase
	C4591001 1224 12241170			24NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject chose to discontinue from trial
	C4591001 1224 12241175	1	17	16DEC2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criteria 5
	C4591001 1226 12261072	1	22	01SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/MYALGIA
		1	65	14OCT2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/MYALGIA

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1226 12261080	2	176	23FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Concomitant COVID-19 vaccine
	C4591001 1226 12261085	2	176	23FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Concomitant Covid-19 Vaccine
	C4591001 1226 12261205	2	51	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject did not want to continue in the study.
	C4591001 1226 12261272	2	28	07OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject withdrew consent due unavailability.
		2	28	07OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject does not want to continue with protocol procedures.
	C4591001 1226 12261301	2	136	27JAN2021	VACCINATION	LOST TO FOLLOW-UP	Multiple unsuccessful contacts
		2	136	27JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Multiple unsuccessful contacts
	C4591001 1226 12261409	1	44	07OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject did not want to continue in the studies procedures.
		1	44	07OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject has no more availability to continue in the study.
	C4591001 1226 12261455	2	127	23JAN2021	REPEAT SCREENING 1	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject took another vaccine.
		2	136	01FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Concomitant COVID-19 vaccine
	C4591001 1226 12261894	1	5	29SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	The subject had a RT-PCR test COVID-19, so he was discontinued from the study, not receiving the V2.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1226 12261927	2	20	24NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject do not want to keep in the study
		2	20	24NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient decided to withdraw informed consent
	C4591001 1226 12262108	1	20	27OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1226 12262132	2	96	16FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	The subject received the first dose of the vaccine Oxford
		2	96	16FEB2021	REPEAT SCREENING 1	NO LONGER MEETS ELIGIBILITY CRITERIA	Concomitant COVID-19 Vaccine
	C4591001 1226 12262136	2	55	27JAN2021	VACCINATION	LOST TO FOLLOW-UP	Multiple unsuccessful contacts
		2	55	27JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Multiple unsuccessful contacts
	C4591001 1226 12262138	2	90	27JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Concomitant COVID-19 Vaccine
	C4591001 1226 12262189	1	14	27OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1226 12262267	1	2	18OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criteria 5
	C4591001 1226 12262313	1	46	03DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	professional reasons
		1	46	03DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	professional reasons

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1229 12291043	2	108	04FEB2021	FOLLOW-UP	OTHER	Subject is incarcerated
	C4591001 1229 12291083†	2	76	05JAN2021	FOLLOW-UP	DEATH	DEATH/COVID-19 PNEUMONIA
	C4591001 1229 12291135†	2	114	18FEB2021	REPEAT SCREENING 1	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject has decided to fall pregnant.
	C4591001 1229 12291204	1	30	11NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
		1	30	11NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject has withdrawn from the study.
	C4591001 1230 12301045†	1	22	20OCT2020	VACCINATION	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY
	C4591001 1230 12301063	2	135	04MAR2021	VACCINATION	LOST TO FOLLOW-UP	PARTICIPANT LOST TO FOLLOW UP. SEVERAL ATTEMPTS WAS MADE TO CONTACT PARTICIPANT WITHOUT ANY SUCCESS
		2	135	04MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	PARTICIPANT LOST TO FOLLOW UP. SEVERAL ATTEMPTS WAS MADE TO CONTACT PARTICIPANT WITHOUT ANY SUCCESS
	C4591001 1230 12301065	2	97	02MAR2021	VACCINATION	WITHDRAWAL BY SUBJECT	Participant translocated and will no longer be able to attend site visits
		2	97	02MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Participant confirmed that he has translocated. Attending additional visits will be difficult.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1230 12301113	1	123	01FEB2021	VACCINATION	WITHDRAWAL BY SUBJECT	WITHDREW CONSENT, PARTICIPANT RELOCATED
		1	123	01FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Participant informed site that he is unable to attend any further site activities.
	C4591001 1230 12301148	1	23	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Patient confirmed re-location for work purposes not foreseen. Not able to attend study visits
		1	23	28OCT2020	FOLLOW-UP	OTHER	Participant relocated and cannot attend study procedures.
	C4591001 1230 12301150	1	23	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew their consent.
		1	23	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject cannot commit to all the study procedures.
	C4591001 1231 12311027	2	154	08MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	the participant who reports having applied the SARS-CoV-2 vaccine (trade name SINOPHARM)
	C4591001 1231 12311031	1	37	15SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311054	1	45	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject refers that the decision to stop participating in the study is due to lack of time
		1	45	24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	No time necessary to comply with the visits and the demand that it takes to participate in the study
	C4591001 1231 12311062	2	165	12FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	After multiple contact attempts, a registered letter is sent. Subject receives it on 3FEB2021

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12311081	2	179	26FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	a vaccine not related to the study was administered
	C4591001 1231 12311087	1	39	19SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311088	1	48	28SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311100	2	141	19JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	cannot comply with scheduled visits due to currently residing in Spain.
	C4591001 1231 12311145	2	186	05MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	participant reports having applied the COVID-19 SINOPHARM vaccine.
	C4591001 1231 12311147	1	7	19AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311189	1	39	21SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311191	1	32	14SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311195	1	40	22SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311200	1	22	04SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not sign amendment 5 because he did not agree

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	22	04SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the subject did not sign amendment 5 because he did not agree
	C4591001 1231 12311230	2	127	08JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	The participant applied the Gam-COVID-Vac vaccine (trade name Sputnik V) on 07 JAN 2021.
	C4591001 1231 12311237	2	188	08MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	the participant reports having applied the Astrazeneca ChAdOx1 (AZS1222) vaccine.
	C4591001 1231 12311342	2	132	13JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	personal reasons
	C4591001 1231 12311356	1	64	17OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The volunteer did not specify the reason why she decided to stop participating.
		1	64	17OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The volunteer did not specify the reason why she decided to stop participating.
	C4591001 1231 12311374	1	31	14SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
		1	31	14SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
	C4591001 1231 12311391	1	14	28AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	COVID 19 DIAGNOSIS
		1	112	04DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	contact attempts: phone call 26OCT, 27OCT, 28OCT mail 28OCT, 29OCT. registered letter 06NOV
	C4591001 1231 12311402	1	30	13SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12311409			15AUG2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/SYNCOPE
				15AUG2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/VOMITING
	C4591001 1231 12311431	1	27	10SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject is afraid of exposure to COVID-19 in next study visits
		1	27	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	you fear going to a health institution and that this will expose you to be reinfected by SARS-COV2
	C4591001 1231 12311441	1	28	11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	for having moved to Gualeguaychu (Province of Entre Rios)
		1	28	11SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	for having moved to Gualeguaychu (Province of Entre Rios)
	C4591001 1231 12311443	1	24	07SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	COVID-19 positive
	C4591001 1231 12311473	1	29	12SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311516			13OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	does not want to continue with the controls, after informing you that it was discontinued.
	C4591001 1231 12311522	2	94	10DEC2020	VACCINATION	LOST TO FOLLOW-UP	Due to lack of response from the subject it is considered as lost to follow up
		2	94	10DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	due to lack of response from the subject it is consider lost to follow up
	C4591001 1231 12311540	2	141	25JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject referred will to receive another COVID-19 vaccine

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12311557	2	46	19OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	He believes that received a placebo and therefore has no interest in continuing with further control
		2	46	19OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject THINKS received placebo, so withdrew consent
	C4591001 1231 12311559	1	28	12SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
		1	28	12SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject decided to withdraw consent
	C4591001 1231 12311568	1	37	21SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311577	2	57	02NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons
	C4591001 1231 12311593	2	147	01FEB2021	VACCINATION	LOST TO FOLLOW-UP	After multiple unanswered phone calls, a certified letter was sent and it was never responded.
		2	147	01FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Volunteer with loss of follow-up
	C4591001 1231 12311641	1	29	13SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311656	1	40	24SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311816	1	31	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12311894	1	44	30SEP2020	VACCINATION	LOST TO FOLLOW-UP	Loss of contact with the volunteer after repeated attempts.
		1	44	30SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	After repeated attempts to contact the volunteer, a registered letter is sent without a response.
	C4591001 1231 12311926			18AUG2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/SYNCOPE
	C4591001 1231 12311973	2	43	20OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The volunteer communicated his desire to withdraw consent to participate in the study when the alarm
		2	43	20OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The volunteer communicated his desire to withdraw consent to participate in the study when the alarm
	C4591001 1231 12311975	2	146	10FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	The participant refers to having applied the Gam-COVID-Vac vaccine (trade name Sputnik V) on 09FEB
	C4591001 1231 12311991	1	21	07SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject decided to withdraw consent
		1	21	07SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject decided to withdraw consent
	C4591001 1231 12311996	2	60	06NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to going to live abroad.
	C4591001 1231 12312034	2	167	22FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Due to the impossibility of contacting the volunteer
	C4591001 1231 12312037	2	153	08FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	personal reasons

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12312176			19AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject randomized for error
	C4591001 1231 12312186	2	35	13OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal and work issues.
		2	35	13OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal and work issues.
	C4591001 1231 12312244	1	23	10SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312267	2	174	01MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Attempts were made to contact the volunteer by email and by phone with no response for more than 20d
	C4591001 1231 12312320	1	61	18OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject with previous clinically or microbiological diagnosis of COVID-19
	C4591001 1231 12312326	1	34	21SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312334	1	32	19SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
		1	157	22JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	After repeated attempts and no response to the certified letter, the Loss of Follow-up is determined
	C4591001 1231 12312361	1	68	25OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Inability to attend visits for work reasons
		1	68	25OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdraw consent due to personal reasons

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12312365	1	28	15SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
		1	56	13OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject decided to withdraw consent due to lack of time
	C4591001 1231 12312403	1	24	11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The patient does not want to take the second dose.
	C4591001 1231 12312451	1	23	11SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Participants who are willing and able to comply with all scheduled visits, vaccination plan, lab...
	C4591001 1231 12312483			20AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	subject randomized in error
	C4591001 1231 12312528	2	123	11JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	On JAN-9-2021, subject received the Gam-COVID-Vac vaccine (trade name Sputnik V).
	C4591001 1231 12312559	1	23	11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject is available to attend the protocol visits
	C4591001 1231 12312577	1	9	28AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/METASTASES TO CENTRAL NERVOUS SYSTEM
	C4591001 1231 12312594	1	77	04NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Stop participating for personal reasons
		1	77	04NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdraws his consent for personal reasons
	C4591001 1231 12312623	1	30	18SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject refuse to receive 2nd dose due to personal reasons but continue with other study procedures

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12312660	1	56	14OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312713	2	35	14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reason.
	C4591001 1231 12312752	1	40	29SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312759	2	36	16OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the volunteer reported her desire to withdraw consent to participate in the study
		2	36	16OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the volunteer reported her desire to withdraw consent to participate in the study
	C4591001 1231 12312763	1	35	24SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312822	2	185	12MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Due to the impossibility of contacting the volunteer, the Loss of Follow-up is determined
	C4591001 1231 12312848	1	29	18SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdraws consent. Subject declares she does not want to be part of the research study
		1	29	18SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdraws consent. Subject declares she does not want to be part of the research study
	C4591001 1231 12312851	2	105	24DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	personal reasons
	C4591001 1231 12312856	2	133	19JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	the participant recieved the Gam-COVID-Vac vaccine (trade name Sputnik V) on 18-JAN-2021

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12312858	2	142	29JAN2021	VACCINATION	LOST TO FOLLOW-UP	after many attempts of contact and no response to certified letter. it is consider lost to follow up
		2	142	29JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	after many attempts of contact and no response to certified letter. it is consider lost to follow up
	C4591001 1231 12312916	1	20	09SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19.
	C4591001 1231 12312982	2	15	23SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
		2	15	23SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrawal of consent for personal reasons
	C4591001 1231 12313030	2	37	16OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The decision to stop participating is due to personal reasons.
		2	37	16OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The decision to stop participating is due to personal reasons.
	C4591001 1231 12313059	2	120	11JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	The participant received the Gam-COVID-Vac vaccine (trade name Sputnik V) on 09JAN2021
	C4591001 1231 12313068	1	23	13SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313069	1	35	25SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313115	1	20	10SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12313125	1	24	14SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313140	2	165	25FEB2021	REPEAT SCREENING 1	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject does not meet the following inclusion criteria: "Healthy participants(continues in comment)
	C4591001 1231 12313175	1	32	22SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject refuses to receive the second dosis of the investigation product
	C4591001 1231 12313207	1	21	11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The volunteer wishes to have a child with his current partner in the short term
		1	21	11SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the volunteer wants to have a child in the short term
	C4591001 1231 12313211	1	11	01SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19.
	C4591001 1231 12313376	1	22	13SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	being written phase 2/3 does not assure you that the safety of the product has been fully evaluated
		1	22	13SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	being written phase 2/3 does not assure you that the safety of the product has been fully evaluated
	C4591001 1231 12313393	2	95	14DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject has not answered phone calls since 11-6 and did not responded to the sended certified letter
	C4591001 1231 12313395	1	23	14SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313428	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The patient decided not to apply the second dose.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12313443			23AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	randomized, no vaccinated
	C4591001 1231 12313449	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject refused to receive the second dose due to the previous medication dosis error.
	C4591001 1231 12313454	1	93	23NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	He referred to his recruiter his wish to be withdrawn from the study. He claimed 'personal reasons'.
	C4591001 1231 12313459	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject made the decision not to receive the second vaccination
	C4591001 1231 12313467	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not agree to be vaccinated a second time,but will continue in the study
	C4591001 1231 12313469	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not want to receive a second dose but did continue in the study
	C4591001 1231 12313479	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject decided not to received second dose of the investigational product
	C4591001 1231 12313486	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not agree to be vaccinated a second time,but will continue in the study
	C4591001 1231 12313492	1	28	19SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not agree to be vaccinated a second time,but will continue in the study
		1	136	05JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	personal reasons

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12313497	1	25	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not agree to be vaccinated a second time, but will continue in the study
	C4591001 1231 12313498	1	25	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not agree to be vaccinated a second time, but will continue in the study
	C4591001 1231 12313506	1	25	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject refused to receive the second dose of treatment due to medication error in the first dose.
	C4591001 1231 12313509	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject did not agree to receive the second dose of the vaccine but continues in the Study
	C4591001 1231 12313510	1	48	09OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criteria: Previous diagnosis (clinical or microbiological) of COVID-19
	C4591001 1231 12313512	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject refused to receive the second dose of the treatment due to the medication error
	C4591001 1231 12313514	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject declined to receive the second vaccination
	C4591001 1231 12313517	1	27	18SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject declined to receive the second vaccination
	C4591001 1231 12313518	1	25	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Did not accept to receive second dose but accept continue with the rest of study procedures
	C4591001 1231 12313519	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Did not accept to receive second dose but accept continue with the rest of study procedures

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12313528	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject declined to receive the second vaccination
	C4591001 1231 12313534	1	28	19SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	medication error in V1, the subject decided not to vaccinate in V2
	C4591001 1231 12313537	1	25	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	medication error in V1, subject decided not to vaccinate in V2
	C4591001 1231 12313541	1	26	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject did not receive the second vaccination but continued otherwise with study procedures
	C4591001 1231 12313546	1	26	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject did not receive the second vaccination but continued otherwise with study procedures
	C4591001 1231 12313551	1	27	18SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject did not agree to receive the second dose, but continues in the study
	C4591001 1231 12313554	1	28	19SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject did not agree to receive the second dose, but continues in the study
	C4591001 1231 12313609	2	44	26OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Withdrawal by subject due to personal (work) issues.
		2	44	26OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal (work) issues.
	C4591001 1231 12313619	2	43	27OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal issues.
		2	43	27OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal issues.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12313622	1	24	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Healthy participants eligible for inclusion in the study and Previous diagnosis of COVID-19
	C4591001 1231 12313657	1	36	28SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313697	2	141	02FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	protocol deviation. subject received plasma as part of its COVID-19 treatment
	C4591001 1231 12313699	2	44	27OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	wants to leave the study
		2	44	27OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	wants to leave the study
	C4591001 1231 12313758	1	44	06OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313788	2	58	09NOV2020	VACCINATION	LOST TO FOLLOW-UP	The subject does not respond to repeated calls
		2	58	09NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	The subject does not respond to repeated calls
	C4591001 1231 12313823	2	45	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons.
		2	45	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons.
	C4591001 1231 12313851	2	40	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Personal reason that he preferred not to share
		2	40	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Personal reason that he preferred not to share

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12313869			25AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the volunteer requests that she be withdrawn from the study
	C4591001 1231 12313872	2	146	05FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The reasons that led him to make this decision are unknown.
	C4591001 1231 12313902	2	177	08MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons.
	C4591001 1231 12313906	2	120	12JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons.
	C4591001 1231 12313955	2	30	14OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to strict personal family causes.
		2	30	14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to strict personal family causes
	C4591001 1231 12313981	2	45	29OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The decision to stop participating must be a move to the province of Santiago del Estero.
		2	45	29OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The decision to stop participating must be a move to the province of Santiago del Estero.
	C4591001 1231 12314030	2	37	23OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons.
		2	37	23OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons
	C4591001 1231 12314046	2	127	18JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	The participant applied the Gam-COVID-Vac vaccine on 06 JAN 2021.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12314134	1	20	14SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12314179	1	30	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent after visit 1
		1	30	24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent after visit 1
	C4591001 1231 12314266	1	22	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
		1	22	16SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
	C4591001 1231 12314314	1	27	21SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
		1	27	21SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature.
	C4591001 1231 12314324	2	120	12JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	The participant received the Gam-COVID-Vac vaccine (trade name Sputnik V) on 12JAN2021
	C4591001 1231 12314381	1	55	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not answer phone call or certified letter. Contact is considered lost
		1	55	20OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject did not answer phone or certified letter. Contact is consider lost
	C4591001 1231 12314492	1	20	15SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
		1	142	15JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	12 telephone contact attempts. 2 email contact attempts. 1 certified letter sent.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12314580	1	33	28SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12314590	1	15	10SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The volunteer states that the decision to stop participating in the study is of a personal nature.
		1	15	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The volunteer states that the decision to stop participating in the study is of a personal nature.
	C4591001 1231 12314700	1	22	18SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12314713	1	22	18SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject refused to receive second dose of investigation product
	C4591001 1231 12314848	1	20	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
		1	64	30OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	after failed attempts of contact by phone and certified letter, it is considered lost of follow up
	C4591001 1231 12314853	2	43	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	unforeseen move out of the country, with no probable date of return.
		2	43	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	unforeseen move out of the country, with no probable date of return.
	C4591001 1231 12314923	1	31	27SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject not being able to continue attending visits.
		1	31	27SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject not being able to continue attending visits.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12314964	2	48	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	The volunteer does not answer calls. Contact was lost, the study was withdrawn
		2	48	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	The volunteer does not answer calls. Contact was lost, the study was withdrawn
	C4591001 1231 12314974	2	118	11JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	the participant reports having applied the Gam-COVID-Vac vaccine (trade name Sputnik V)
	C4591001 1231 12314984	1	21	17SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
		1	36	02OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	It is due to having been discontinued from the study.
	C4591001 1231 12314987	2	82	06DEC2020	FOLLOW-UP	DEATH	DEATH/CARDIO-RESPIRATORY ARREST
	C4591001 1231 12315308			16SEP2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject randomized in error
	C4591001 1231 12315357	1	13	10SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject does not specify the reasons for withdrawing from the study
		1	13	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject does not specify the reasons for withdrawing from the study
	C4591001 1231 12315386	2	161	25FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject was vaccinated with Gam-COVID-Vac (trade name Sputnik V).
	C4591001 1231 12315429	1	37	05OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/INJECTION SITE PAIN
		1	37	05OCT2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/INJECTION SITE PAIN

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12315568	2	154	19FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	says she is a teacher and wants to receive another vaccine against COVID-19
	C4591001 1231 12315578	2	158	23FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Vaccine not related to the study is applied in Colombia
	C4591001 1231 12315600	1	22	21SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject refused to receive second dose of investigation product
	C4591001 1232 12321002	2	5	06SEP2020	VACCINATION	LOST TO FOLLOW-UP	Participant cannot be contacted, to be dropped from study
		2	5	06SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject did not remain in study for follow-up
	C4591001 1232 12321009	2	4	06SEP2020	VACCINATION	LOST TO FOLLOW-UP	Participant cannot be contacted, to be dropped from study
		2	4	06SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Participant cannot be contacted, to be dropped from study
	C4591001 1232 12321015	1	21	02SEP2020	VACCINATION	LOST TO FOLLOW-UP	patient is labeled a "no show"
		1	21	02SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	patient labeled as a "no show"
	C4591001 1232 12321037			18AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject Randomized in Error
	C4591001 1232 12321093	2	29	13OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	treatment period was not completed
		2	29	13OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Treatment period was not completed

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1232 12321094	2	27	13OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject relocated out of state
		2	27	13OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdrew Consent
	C4591001 1232 12321142	1	24	23SEP2020	VACCINATION	OTHER	re-joined trial in the revaccination open label portion
	C4591001 1232 12321175	1	23	25SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/HYPERTENSION
	C4591001 1232 12321202	2	117	25JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received non-pfizer COVID-19 vaccine at work and no longer qualified for the study
	C4591001 1232 12321210	2	67	06DEC2020	VACCINATION	LOST TO FOLLOW-UP	multiple attempts to contact patient, phone is no longer in service
		2	67	06DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts to contact patient, phone is no longer in service
	C4591001 1232 12321223	2	1	30SEP2020	VACCINATION	LOST TO FOLLOW-UP	Participant cannot be contacted, to be dropped from study
		2	1	30SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Participant cannot be contacted, to be dropped from study
	C4591001 1232 12321233	1	1	10SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from the site
		1	1	10SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from the site

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1232 12321244	1	1	11SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return the sites calls
		1	1	11SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is not returning any of the sites phone calls. Will not be rejoining.
	C4591001 1232 12321266	2	1	15OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V3 and has not returned calls from the site
		2	1	15OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V3 and has not returned calls from the site
	C4591001 1232 12321287	1	21	21OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V3 and has not returned calls from the site
		1	21	21OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V3 and has not returned calls from the site
	C4591001 1232 12321289	2	1	21OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V3 and phone number given to site was not in service
		2	1	21OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V3 and phone number given to site was not in service
	C4591001 1232 12321293	1	22	22OCT2020	VACCINATION	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY
	C4591001 1232 12321299	1	1	06OCT2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION/HYPERTENSION
		1	24	29OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Pt never returned for V2./HYPERTENSION
	C4591001 1232 12321361	1	123	18FEB2021	VACCINATION	WITHDRAWAL BY SUBJECT	Subject decided to withdraw from study due to relocation

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	123	18FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject has moved and decided to withdraw consent.
	C4591001 1232 12321370	2	29	08DEC2020	VACCINATION	OTHER	Could not get in contact with subject after multiple attempts
	C4591001 1232 12321396	1	1	23OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from the site
		1	1	23OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from the site
	C4591001 1232 12321400	1	1	23OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from site.
		1	1	23OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not return for V2 and would not return calls from the site.
	C4591001 1232 12321412	1	1	27OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from the site
		1	1	27OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from the site
	C4591001 1232 12321419	1	1	27OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from the site
		1	1	27OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from the site
	C4591001 1232 12321425	1	1	28OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from the site
		1	1	28OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from the site

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1232 12321428	2	1	23NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V3 and has not returned calls from the site
		2	1	23NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V3 and has not returned calls from the site
	C4591001 1232 12321429	1	1	28OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V2 and has not returned calls from the site
		1	1	28OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V2 and has not returned calls from the site
	C4591001 1232 12321430	2	1	25NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V3 and has not returned calls from the site
		2	1	25NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V3 and has not returned calls from the site
	C4591001 1232 12321434	2	1	19NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V3 and has not returned calls from the site
		2	20	08DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject did not attend V3 and has not returned calls from the site
	C4591001 1235 12351027	1	18	23SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	COVID-19 positive with symptoms. Will not receive Vaccine 2.
	C4591001 1235 12351071	1	9	22SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criteria 5
	C4591001 1235 12351167			09OCT2020	FOLLOW-UP	PROTOCOL DEVIATION	randomized but not vaccinated-met exclusion criteria

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1235 12351187	1	9	24OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	meets exclusion #5
	C4591001 1241 12411208	2	170	25FEB2021	OPEN LABEL TREATMENT	PREGNANCY	PREGNANCY/MATERNAL EXPOSURE DURING PREGNANCY
	C4591001 1241 12411211	2	175	02MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received another Covid vaccine
	C4591001 1241 12411260	1	12	30AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Discontinued. Exc#5
	C4591001 1241 12411279	1	23	10SEP2020	VACCINATION	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY
	C4591001 1241 12411449	2	151	11FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received another Covid-19 vaccine
	C4591001 1241 12411465	2	156	18FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject used another covid-19 vaccine
	C4591001 1241 12411514	2	148	17FEB2021	OPEN LABEL TREATMENT	PREGNANCY	PREGNANCY/MATERNAL EXPOSURE DURING PREGNANCY
	C4591001 1241 12411688	1	13	27SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Discontinued Exc#5
	C4591001 1241 12411695	1	4	18SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Discontinued Exc#5

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1241 12411766	1	24	09OCT2020	VACCINATION	PREGNANCY	PREGNANCY/MATERNAL EXPOSURE DURING PREGNANCY
	C4591001 1241 12412120	2	114	11FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received another Covid-19 vaccine
	C4591001 1241 12412355	1	22	09NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Discontinued Exc#5
	C4591001 1241 12412369	2	111	01MAR2021	OPEN LABEL TREATMENT	PREGNANCY	PREGNANCY/MATERNAL EXPOSURE DURING PREGNANCY
	C4591001 1241 12412411	2	119	08MAR2021	OPEN LABEL TREATMENT	PREGNANCY	PREGNANCY/MATERNAL EXPOSURE DURING PREGNANCY
	C4591001 1246 12461025	1	22	19OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/URTICARIA
	C4591001 1247 12471107	2	29	17NOV2020	VACCINATION	LOST TO FOLLOW-UP	Pt did not arrive for Visit 3. After multiple attempts by site staff, pt still did not arrive for V3
	C4591001 1247 12471121	2	10	30OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Patient withdrew after motorcycle accident (Undisclosed medical condition)
		2	10	30OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient withdrew after motorcycle accident (Undisclosed medical condition)
	C4591001 1247 12471136	2	29	18NOV2020	VACCINATION	LOST TO FOLLOW-UP	Pt did not arrive for Visit 3. After multiple attempts by site staff, pt still did not arrive for V3

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1247 12471149	1	1	01OCT2020	VACCINATION	LOST TO FOLLOW-UP	Patient not answering calls from site; possibly relocated
		1	1	01OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Patient not answering calls from site; could possibly have relocated
	C4591001 1247 12471151	1	22	22OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Pt. sold e-diary smart phone. Does not meet eligibility Inclusion 2. E-diary deactivated.
	C4591001 1248 12481018			28AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdrew Consent
	C4591001 1248 12481025			29AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdrew Consent
	C4591001 1248 12481046	1	66	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	Missed V2 on 20Sep2020; site has been unable to contact subject despite multiple calls.
		1	66	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Please see EOT page
	C4591001 1248 12481048	1	66	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject missed V2 on 20Sep2020; multiple attempts to reach subject were unsuccessful.
		1	66	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Please see EOT page.
	C4591001 1248 12481060			02SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Participant withdrew consent
	C4591001 1248 12481110	1	59	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject was no show for V2; unable to contact subject.
		1	59	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was no show for V2; unable to contact subject.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1248 12481114	2	1	30SEP2020	VACCINATION	OTHER	Participant is pending a site transfer.
	C4591001 1248 12481138	2	125	02FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject said she no longer wishes to participate in the study. No reason given.
	C4591001 1248 12481175	1	22	06OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1248 12481198	2	1	06OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up
		2	1	06OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1248 12481199	1	35	21OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		1	35	21OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1248 12481206	2	1	09OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up
		2	1	09OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1248 12481218			21SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/SYNCOPE
				21SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/SYNCOPE
	C4591001 1251 12511095	1	21	21SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject wished to withdraw from the study

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	21	21SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1251 12511204			23SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Withdrew consent and would not comply with study procedures
				24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
	C4591001 1251 12511207	1	1	23SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	clinical diagnosis of Covid-19
	C4591001 1254 12541007	2	121	14JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject made a decision to withdraw the study by getting the Moderna vaccine.
	C4591001 1254 12541023	1	25	21SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Per PI, subject no longer meets eligibility criteria by meeting exclusion #1
	C4591001 1254 12541116	1	21	29SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	PATIENT WITHDREW CONSENT
		1	21	29SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject called the site and withdrew consent without any specific reason.
	C4591001 1254 12541142	1	26	07OCT2020	VACCINATION	PREGNANCY	PREGNANCY/MATERNAL EXPOSURE DURING PREGNANCY
	C4591001 1254 12541154	1	135	26JAN2021	VACCINATION	LOST TO FOLLOW-UP	Multiple attempt to contact subject, no responses. Including a certified letter
		1	135	26JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Multiple attempt to contact subject including Certified letter.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1254 12541167	2	92	12JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject was able to get vaccinated with Moderna vaccine and that Pfizer did not act quickly enough.
	C4591001 1258 12581069	2	55	04JAN2021	VACCINATION	WITHDRAWAL BY SUBJECT	subject moved and withdrew consent
		2	55	04JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject moved and withdrew consent
	C4591001 1260 12601049			02SEP2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	hypertension after randomization so withdrawn from study
	C4591001 1260 12601070			04SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	pt withdrawal due to pregnancy partner protocol guidelines
	C4591001 1264 12641018			25AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject randomized but remembered she had an MMR vaccine within last 28 days and would need booster.
	C4591001 1264 12641020	2	178	08MAR2021	VACCINATION	PROTOCOL DEVIATION	Subject left country and missed visit three
	C4591001 1264 12641159	2	101	14JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Moderna vaccine through her employer, and was subsequently discontinued from study.
	C4591001 1265 12651153	2	121	10FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Withdrawn from study due to receiving the COVID vaccine outside of the study.
	C4591001 1269 12691007	2	135	22JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1269 12691014	2	114	31DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject will not have time for the study
	C4591001 1269 12691026	2	99	17DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject discontinued participation
	C4591001 1269 12691047	2	126	18JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject discontinued her participation
	C4591001 1269 12691088	2	165	04MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1270 12701003	2	100	24DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	RECEIVED COVID-19 VACCINE OUTSIDE THE STUDY ON 19DEC2020
	C4591001 1270 12701008	2	106	30DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	RECEIVED COVID-19 VACCINE OUTSIDE THE STUDY ON 28DEC2020
	C4591001 1270 12701041	2	92	21DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WISHES TO RECEIVE PFIZER COVID-19 VACCINE THROUGH EMPLOYER.
	C4591001 1270 12701056	2	116	25FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Participant unwilling to complete further study activities and wishes to received Covid19 vaccine
	C4591001 1270 12701069	2	106	13JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	RECEIVED COVID 19 VACCINE OUTSIDE OF STUDY - PFIZER BIONTECH COVID-19 VACCINE 31DEC2020
	C4591001 1270 12701118	2	85	30DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	RECEIVED COVID-19 VACCINE OUTSIDE THE STUDY ON 26DEC2020

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1270 12701121	2	120	11FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject wishes to no longer participate in study
	C4591001 1270 12701137	2	79	29DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	RECEIVED COVID-19 VACCINE OUTSIDE THE STUDY ON 17DEC2020
	C4591001 1270 12701175	2	66	24FEB2021	VACCINATION	WITHDRAWAL BY SUBJECT	Per LAR/father, request to drop participant, non-compliant with study activities
		2	66	24FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Per LAR/father request to drop participant as has been non-compliant with study activities
	C4591001 1270 12701176	2	66	24FEB2021	VACCINATION	WITHDRAWAL BY SUBJECT	Per LAR/father, request to drop participant, non-compliant with study activities
		2	66	24FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Per LAR/father, request to drop participant as participant is non-compliant with study activities
	C4591001 4444 44441024	2	49	30NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons
		2	49	30NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons
	C4591001 4444 44441025	1	12	02OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 4444 44441044	1	16	06OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Positive COVID-19 Diagnosis
	C4591001 4444 44441048	1	18	08OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Husband is a cancer patient and asked her not to continue for the fear of her going to a hospital

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	18	08OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Husband is a cancer patient and asked her not to continue for the fear of her going to a hospital
	C4591001 4444 44441079	1	22	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	disagree with not knowing whether to receive placebo or research product
		1	22	12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	disagree with not knowing whether to receive placebo or research product
	C4591001 4444 44441103	2	124	12FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to your inability to keep scheduled visits.
	C4591001 4444 44441135			21SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	She does not want to be part of the study due to personal problems.
	C4591001 4444 44441179	1	22	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal problems.
		1	22	12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal problems.
	C4591001 4444 44441224	2	31	12NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	due to the fact that he did not agree to their follow-up for the covid disease
		2	31	12NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	due to the fact that he did not agree to their follow-up for the covid disease
	C4591001 4444 44441273	1	24	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject expressed his decision to stop participating for work reasons.
		1	24	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject expressed his decision to stop participating for work reasons.
	C4591001 4444 44441289	2	96	16JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject does not wish to receive BNT162b2 vaccine

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 4444 44441327	2	123	13FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	voluntary withdrawn from the study due to having received non study vaccinations
	C4591001 4444 44441329	2	81	31DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal issues.
	C4591001 4444 44441477	2	123	11FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal causes.
	C4591001 4444 44441500	2	92	11JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	5 telephone contact attempts. 1 email contact attempt. 1 certified letter sent.
	C4591001 4444 44441522	1	21	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	For work reasons he is unable to complete the visits scheduled by protocol
		1	21	12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	For work reasons he is unable to complete the visits scheduled by protocol
	C4591001 4444 44441560	1	10	02OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Positive COVID-19 diagnosis.
	C4591001 4444 44441569	1	22	14OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons
		1	22	14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons
	C4591001 4444 44441572	1	31	23OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Participant who is willing and able to comply with all study procedures
	C4591001 4444 44441818	1	28	22OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	He refers not being able to continue with the study due to personal problems.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	28	22OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	He refers not being able to continue with the study due to personal problems.
	C4591001 4444 44441928	2	112	04FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	No response to the registered letter sent on 15JAN2021 and after repeated contact attempts.
	C4591001 4444 44441931	1	21	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	For recommendation of his doctor.
	C4591001 4444 44441950	2	83	05JAN2021	VACCINATION	LOST TO FOLLOW-UP	After repeated attempts and no response to the registered letter the loss of follow up is determined
		2	83	05JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	After repeated attempts and no response to the registered letter the loss of follow-up is determined
	C4591001 4444 44441951	1	60	23NOV2020	VACCINATION	LOST TO FOLLOW-UP	30OCT unsuccessful phone call 06NOV registered letter is sent. Still no answer
		1	60	23NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	30OCT unsuccessful phone call 06NOV registered letter is sent. Still no answer
	C4591001 4444 44441979	1	21	15OCT2020	VACCINATION	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY
		1	48	11NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to particular reasons/EXPOSURE DURING PREGNANCY
	C4591001 4444 44442006	2	140	02MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is for personal reasons
	C4591001 4444 44442081	2	145	08MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision is due to "the little collaboration of Pfizer with the Argentine State."

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 4444 44442088	2	87	09JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	The participant received the Gam-COVID-Vac vaccine (trade name Sputnik V) on 02JAN2021
	C4591001 4444 44442107	1	51	16NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	personal motives
		1	51	16NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	personal motives
	C4591001 4444 44442131	2	1	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew his consent after finishing visit 2. No specific reason was given.
		2	1	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew his consent after finishing visit 2. No specific reason was given.
	C4591001 4444 44442194	1	20	16OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating must be traveled abroad.
		1	20	16OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating must be traveled abroad.
	C4591001 4444 44442263	1	24	20OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Will not be able to continue in the trial since she has had to travel abroad for personal reasons
		1	24	20OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Will not be able to continue in the trial since she has had to travel abroad for personal reasons
	C4591001 4444 44442293	1	39	04NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal problems.
		1	39	04NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal problems.
	C4591001 4444 44442319	1	37	02NOV2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/PANIC ATTACK

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
18-55	C4591001 1002 10021008^	1	37	02NOV2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/PANIC ATTACK
		2	205	16DEC2020	FOLLOW-UP	OTHER	Subject moved, unable to continue
65-85	C4591001 1001 10011041^	2	210	27JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Participant received 1 dose of the EUA Pfizer vaccine on 22 Jan 2021.
	C4591001 1001 10011053^	2	245	10MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Participant received MODERNA vaccine outside of study
>55	C4591001 1001 10011099	2	169	04FEB2021	OPEN LABEL TREATMENT	PROTOCOL DEVIATION	second Pfizer vaccine dose received outside of study
	C4591001 1005 10051019	2	134	12JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Early Term due to receiving Moderna covid vaccine
	C4591001 1005 10051214	1	11	13SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/FACIAL PAIN
		1	11	13SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/SWELLING FACE
	C4591001 1005 10051293	1	57	14DEC2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT IS LOST TO FOLLOW UP
		1	57	14DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW UP
	C4591001 1006 10061020	1	36	16SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/CORONARY ARTERY OCCLUSION
		1	36	16SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/CORONARY ARTERY OCCLUSION

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1006 10061147	2	156	05MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Non-study COVID-19 Vaccine
	C4591001 1007 10071101	2	63	21OCT2020	FOLLOW-UP	DEATH	DEATH/CARDIAC ARREST
	C4591001 1007 10071114	1	22	24AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	meets inc #3; Per subI Recent loss of taste & smell, anorexia & dizziness with gait instability
		1	186	04FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071173	2	171	19FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071188	2	133	12JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071237	2	119	06JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071291	2	174	09MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071335	2	58	31DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071347	1	22	05NOV2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/ATRIAL FIBRILLATION

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1008 10081486	2	107	28JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1008 10081639	1	6	24OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Tested positive for COVID 19
	C4591001 1008 10081667	2	119	10MAR2021	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/HEPATIC CANCER
	C4591001 1008 10081697	2	60	14JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent, being vaccinated outside of study in Florida, unable to return to Missouri
	C4591001 1008 10081725	1	18	15NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Tested positive for COVID 19
	C4591001 1009 10091020	1	14	24AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	WITHDRAWAL BY SUBJECT
		1	14	24AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	WITHDRAWAL BY SUBJECT
	C4591001 1009 10091035	2	130	11JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	covid vaccine outside of research study
	C4591001 1009 10091064	2	122	08JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	subject meets exclusion criteria #12
	C4591001 1009 10091157	1	21	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent
		1	21	24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1011 10111181	1	1	08OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/PARAESTHESIA ORAL
	C4591001 1012 10121149	1	53	30OCT2020	VACCINATION	LOST TO FOLLOW-UP	No call now show for two scheduled appointments and no response to certified letter sent.
		1	53	30OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	No call, no show for 2 scheduled visits and no response to certified letter
	C4591001 1013 10131092	2	137	08JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT REQUESTED UNBLINDING.
	C4591001 1013 10131097			06AUG2020	SCREENING	OTHER	SUBJECT WAS ALREADY RANDOMIZED BUT DID NOT MEET CRITERIA FOR VACCINATION. SUBJECT IS DISCONTINUED.
				06AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT DID NOT MEET EXCLUSION #5 BUT WAS ALREADY RANDOMIZED INTO STUDY. DID NO RECEIVE VACCINATION.
	C4591001 1013 10131123	2	70	09NOV2020	VACCINATION	LOST TO FOLLOW-UP	UNKNOWN
		2	70	09NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	UNKNOWN
	C4591001 1013 10131192	1	23	08SEP2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
		1	23	08SEP2020	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1013 10131230	2	119	05JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT DID NOT WANT TO CONTINUE IN STUDY.
	C4591001 1013 10131453	2	99	04JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WANTED TO WITHDRAW TO GET AN EMPLOYER BASED VACCINE.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1013 10131555	2	86	29DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent to get community vaccination.
	C4591001 1013 10131604	2	77	29DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT RECEIVED PFIZER VACCINE IN COMMUNITY.
	C4591001 1013 10131714	1	38	20NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject no longer wishes to participate in study; will not be able to comply with future visits
		1	38	20NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject does not wish to participate in study; unable to be compliant with future visits
	C4591001 1013 10131758	2	90	08FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT NO LONGER WANTED TO PARTICIPATE
	C4591001 1013 10131784	2	80	29JAN2021	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT MOVED OUT OF AREA AND NO LONGER WANTED TO PARTICIPATE.
		2	80	29JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT MOVED OUT OF AREA AND NO LONGER WANTED TO PARTICIPATE.
	C4591001 1016 10161194	2	105	29DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	subject received covid vaccine outside of study
	C4591001 1016 10161282	2	15	18JAN2021	VACCINATION	OTHER	subject able to continue in placebo crossover visits.
	C4591001 1018 10181043	2	179	08MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1018 10181112	2	122	30DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	will get vaccine at workplace.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1018 10181348	2	106	24FEB2021	VACCINATION	WITHDRAWAL BY SUBJECT	unable to make visit for study.
		2	106	24FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Unable to make visits for study
	C4591001 1019 10191010	2	93	02DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up
	C4591001 1019 10191021	2	174	22FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received other Coronavirus vaccine elsewhere.
	C4591001 1019 10191033			13AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent after being randomized.
	C4591001 1019 10191146	2	87	17DEC2020	FOLLOW-UP	DEATH	DEATH/BILIARY CANCER METASTATIC
		2	87	17DEC2020	FOLLOW-UP	DEATH	DEATH/METASTASES TO LIVER
	C4591001 1019 10191223	2	64	16DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Received vaccine elsewhere.
	C4591001 1019 10191229	2	29	12NOV2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT
	C4591001 1019 10191299	1	7	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrawn
		1	7	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent from trial.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1019 10191300			22OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent after being randomized.
	C4591001 1021 10211177	2	114	21JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	patient received COVID-19 vaccine outside of study
	C4591001 1021 10211233	2	106	21JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Patient received COVID vaccine outside of study
	C4591001 1022 10221015			17AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient changed his mind after randomization but before vaccination
	C4591001 1022 10221053	2	159	19FEB2021	OPEN LABEL TREATMENT	ADVERSE EVENT	ADVERSE EVENT/CHILLS
		2	159	19FEB2021	OPEN LABEL TREATMENT	ADVERSE EVENT	ADVERSE EVENT/DIARRHOEA
		2	159	19FEB2021	OPEN LABEL TREATMENT	ADVERSE EVENT	ADVERSE EVENT/HEADACHE
		2	159	19FEB2021	OPEN LABEL TREATMENT	ADVERSE EVENT	ADVERSE EVENT/INJECTION SITE PAIN
		2	159	19FEB2021	OPEN LABEL TREATMENT	ADVERSE EVENT	ADVERSE EVENT/MYALGIA
	C4591001 1022 10221057			25AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient withdrew IFC.
	C4591001 1022 10221150			09SEP2020	FOLLOW-UP	OTHER	IP was quarantined after patient was randomized

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1024 10241053	2	127	15JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient is in Florida, wanted to be vaccinated while there, pt is 85 years old withdrew consent
	C4591001 1024 10241077	1	28	21SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent, will not return to clinic for any visits/procedures- wants no contact
		1	28	21SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient withdrew consent
	C4591001 1024 10241130†	1	9	28OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	patient no longer qualifies for vacc#2 due to meeting exclusion criteria #5
	C4591001 1027 10271191	2	135	13FEB2021	FOLLOW-UP	DEATH	DEATH/ACUTE RESPIRATORY FAILURE
		2	135	13FEB2021	FOLLOW-UP	DEATH	DEATH/COVID-19
	C4591001 1027 10271206†	1	31	30OCT2020	VACCINATION	LOST TO FOLLOW-UP	Site attempted to contact subject on multiple occasions and certified letter was sent.
		1	31	30OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Site attempted to contact subject on multiple occasions and certified letter was sent.
	C4591001 1030 10301094	2	121	02FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	participant received the moderna vaccine
	C4591001 1030 10301115	2	63	15DEC2020	VACCINATION	PROTOCOL DEVIATION	patient never returned for 3rd visit
		2	134	24FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject is planning to receive non-study COVID-19 vaccine
	C4591001 1030 10301116	2	83	04JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	subject never returned for next visit

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1036 10361133	1	60	15DEC2020	VACCINATION	LOST TO FOLLOW-UP	Subject didn't return for V2VX2L and didn't respond to registered letter.
		1	60	15DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject didn't return for V2VX2L and didn't respond to registered letter.
	C4591001 1036 10361140	2	91	10FEB2021	FOLLOW-UP	DEATH	DEATH/INJURY
		2	91	10FEB2021	FOLLOW-UP	DEATH	DEATH/ROAD TRAFFIC ACCIDENT
	C4591001 1037 10371057			24AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT NOT WILLING TO ATTEND VISITS AFTER RANDOMIZATION WAS COMPLETED
	C4591001 1037 10371117			18SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT DID NOT WANT TO WAIT FOR FLU VAX
				18SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject did not want to wait to receive Flu vaccine
	C4591001 1037 10371303	2	123	08MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	PT WANTS TO GET VACCINE IN THE COMMUNITY
	C4591001 1039 10391010	2	71	18NOV2020	FOLLOW-UP	DEATH	DEATH/ARTERIOSCLEROSIS
		2	71	18NOV2020	FOLLOW-UP	DEATH	DEATH/HYPERTENSIVE HEART DISEASE
	C4591001 1039 10391051	2	93	23DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient desires to withdraw from study.
	C4591001 1039 10391142	2	71	17DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Patient received COVID19 vaccine outside of study

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1039 10391201	2	52	31DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient withdrew consent
	C4591001 1042 10421010	1	21	19AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrew consent
		1	21	19AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1042 10421097	2	118	28DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Received Vaccination Outside of Study
	C4591001 1042 10421119	2	127	13JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received EUA vaccine outside of study without notifying site
	C4591001 1042 10421134	2	111	28DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Moderna EUA vaccine
	C4591001 1042 10421139	2	156	10FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received vaccine outside of study
	C4591001 1042 10421152	2	121	14JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1042 10421156	2	122	13JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received vaccine outside of study
	C4591001 1042 10421164	2	105	28DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrew consent

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1042 10421174	2	114	12JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrew consent
	C4591001 1042 10421187	2	107	05JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject Received Vaccination outside of study
	C4591001 1044 10441113			11SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent to participate
	C4591001 1046 10461080	2	96	15DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdrew
	C4591001 1046 10461082	2	115	04JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Decision
	C4591001 1046 10461251	2	84	23DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	non-study coronavirus vaccine
	C4591001 1046 10461259	1	22	05OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject Decision to With Draw
		1	22	05OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Decision
	C4591001 1047 10471002	2	167	22FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew from study
	C4591001 1047 10471011	2	11	18SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent
		2	11	18SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient withdrew consent

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1047 10471026	2	99	17DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1047 10471114	2	30	22OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT
	C4591001 1047 10471252	1	22	12OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	The subject was diagnosed and had symptomatic Covid
	C4591001 1047 10471280	2	104	25JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1047 10471281	2	104	25JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1052 10521020	1	21	10SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrawl by subject
		1	21	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawl by patient
	C4591001 1052 10521024	2	166	26FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal by subject
	C4591001 1052 10521037	2	120	12JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	discontinued
	C4591001 1052 10521045	2	110	05JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal by subject

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1052 10521050	2	106	30DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal by subject
	C4591001 1052 10521062	1	26	25SEP2020	VACCINATION	LOST TO FOLLOW-UP	n/a
	C4591001 1052 10521127	1	26	25SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	los to follow up
	C4591001 1052 10521127	2	111	25JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received vaccination outside of study after being prompted not to by site staff
	C4591001 1054 10541024	2	152	10MAR2021	VACCINATION	OTHER	Visit 3 is now way OOW, but PI doesn't want to deem pt LTFU, yet. Last CL sent on 19Feb21.
	C4591001 1054 10541059	2	121	15JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received non-study covid-19 vaccination on 06Jan21.
	C4591001 1054 10541062	2	135	29JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Pt received non-study Pfizer COVID-19 vaccine.
	C4591001 1054 10541071			28AUG2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	Re-screened and randomized as subj 10541083.
	C4591001 1054 10541126	2	122	27JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt. requested to be unblinded, despite not being eligible to be unblinded, per vaccination tiers.
	C4591001 1054 10541167	2	89	04JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Unblinding of subject occurred due to possible future non-study COVID-19 vaccination.
	C4591001 1054 10541173	2	123	08FEB2021	VACCINATION	ADVERSE EVENT	ADVERSE EVENT

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1054 10541175			21SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent due to personal reasons
	C4591001 1054 10541186	1	1	23SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DIZZINESS
	C4591001 1054 10541195	1	1	23SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/NAUSEA
	C4591001 1054 10541195	2	68	12JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Unblinding of subject occurred due to future non-study COVID-19 vaccination.
	C4591001 1055 10551039	1	23	04SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject willing to continue in study off medication
	C4591001 1055 10551242	2	1	12OCT2020	VACCINATION	OTHER	Completed visit 2, didn't complete visit 3 he relocated out of state. Will complete visit 4 by phone
	C4591001 1056 10561008	2	185	11MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	participant explained that she move out of the town.
	C4591001 1056 10561018	1	19	09SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT STATED SHE DOES NOT WANT TO CONTINUE HER PARTICIPATION IN THE STUDY.
	C4591001 1056 10561024	1	19	09SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1056 10561024	2	84	02DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT REFERRED SHE WANTED TO WITHDREW CONSENT DURING A TELEPHONE CONTACT ON 12/02/2020.
	C4591001 1056 10561078			28AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt. referred she did not want to continue in the study.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1056 10561079	1	55	21OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT STATED SHE IS SCARED OF THE VACCINE AFTER WATCHING NEWS REPORT ABOUT SAFETY CONCERNS.
		1	55	21OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT STATED SHE IS SCARED OF THE VACCINE AFTER WATCHING NEWS REPORT ABOUT SAFETY CONCERNS.
	C4591001 1056 10561083	2	30	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	PT STATED HE HAS TO LEAVE THE COUNTRY DUE TO A PERSONAL EMERGENCY AND HE WILL NOT BE ABLE TO CONTINUE
		2	30	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	PT STATED HE HAS TO LEAVE THE COUNTRY DUE TO A PERSONAL EMERGENCY AND HE WILL NOT BE ABLE TO CONTINUE
	C4591001 1056 10561120	1	25	25SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject expressed his desire to withdraw his participation in the trial.
		1	25	25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject expressed his desire to withdraw his participation in the trial.
	C4591001 1056 10561123	1	24	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject states he doesn't want to continue in the study.
		1	24	24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject states he doesn't want to continue in the study.
	C4591001 1056 10561139	2	83	15DEC2020	VACCINATION	LOST TO FOLLOW-UP	AFTER MULTIPLE ATTEMPTS TO CONTACT SUBJECT, PI DECIDED TO DISCONTINUE SUBJECT FROM STUDY.
		2	83	15DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	AFTER MULTIPLE ATTEMPTS TO CONTACT SUBJECT, PI DECIDED TO DISCONTINUE SUBJECT FROM STUDY.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1056 10561275	1	51	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
		1	51	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
	C4591001 1056 10561276	1	20	06OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT STATED HE DOES NOT WANT TO CONTINUE PARTICIPATING IN THE TRIAL.
		1	20	06OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT STATED HE DOES NOT WANT TO CONTINUE PARTICIPATING IN THE TRIAL.
	C4591001 1056 10561298	1	50	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
		1	50	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
	C4591001 1056 10561337	1	83	15DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject referred he wanted to Withdrew consent from study.
		1	83	15DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject referred he wanted to Withdrew consent from study.
	C4591001 1056 10561371	1	38	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
		1	38	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
	C4591001 1056 10561381	1	51	20NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT INFORMED US SHE WANTED TO WITHDREW CONSENT.
		1	51	20NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT INFORMED US SHE WANTED TO WITHDREW CONSENT.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1056 10561426	1	64	09DEC2020	VACCINATION	LOST TO FOLLOW-UP	AFTER MANY ATTEMPTS TO CONTACT THIS SUBJECT AND A CERTIFIED LETTER SENT, PI DECIDED TO D/C PT.
		1	64	09DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	AFTER MANY ATTEMPTS TO CONTACT THIS SUBJECT AND A CERTIFIED LETTER SENT, PI DECIDED TO D/C PT.
	C4591001 1056 10561479	2	66	06JAN2021	VACCINATION	LOST TO FOLLOW-UP	After multiple unsuccessful TCs to Pt. and emergency contact, and a Certified letter, Pt. was D/C.
		2	66	06JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	After multiple unsuccessful TCs to Pt. and emergency contact, and a Certified letter, Pt. was D/C.
	C4591001 1056 10561485	2	90	03FEB2021	VACCINATION	LOST TO FOLLOW-UP	AFTER MANY UNSUCCESSFUL ATTEMPTS TO CONTACT PT. INCLUDING A CERTIFIED LETTER, PI DECIDED TO D/C
		2	90	03FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	AFTER MANY UNSUCCESSFUL ATTEMPTS TO CONTACT PT. INCLUDING A CERTIFIED LETTER, PI DECIDED TO D/C
	C4591001 1056 10561487	2	92	02FEB2021	VACCINATION	LOST TO FOLLOW-UP	AFTER MANY UNSUCCESSFUL ATTEMPTS TO CONTACT PT. AND A CERTIFIED LETTER, PI DECIDED TO D/C.
		2	92	02FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	AFTER MANY UNSUCCESSFUL ATTEMPTS TO CONTACT PT. AND A CERTIFIED LETTER, PI DECIDED TO D/C.
	C4591001 1056 10561625	1	50	16DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT STATED SHE WANTED TO WITHDREW CONSENT FROM STUDY DURING A TELEPHONE CALL ON 12/16/2020.
		1	50	16DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT STATED SHE WANTED TO WITHDREW CONSENT FROM STUDY DURING A TELEPHONE CALL ON 12/16/2020.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1057 10571094	2	106	28DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Due to disclosure of non-study COVID-19 vaccine.
	C4591001 1057 10571114	2	93	17DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	patient received Pfizer vaccine outside of trial
	C4591001 1066 10661074	2	51	30OCT2020	VACCINATION	LOST TO FOLLOW-UP	unable to reach subject after several phone attempts and certified letter
	C4591001 1066 10661350	2	51	30OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject unable to be reached after several attempts
	C4591001 1068 10681107	1	16	03NOV2020	VACCINATION	DEATH	DEATH/MYOCARDIAL INFARCTION
	C4591001 1068 10681107	2	83	16DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Withdrawal by subject due to receiving covid-19 vaccine outside of study
	C4591001 1071 10711023	1	12	23AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/CORONARY ARTERY DISEASE
	C4591001 1071 10711049	1	17	28AUG2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/CORONARY ARTERY DISEASE
	C4591001 1071 10711049	2	140	21JAN2021	OPEN LABEL TREATMENT	PROTOCOL DEVIATION	SUBJECT REFUSED TO STAY FOR POST VACCINATION OBSERVATION
	C4591001 1071 10711049	2	140	21JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT REFUSED TO STAY FOR OBSERVATION PERIOD
	C4591001 1071 10711063	1	13	31AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	13	31AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1071 10711135	2	146	17FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW UP
	C4591001 1071 10711139	2	145	22FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW UP
	C4591001 1071 10711169	1	31	15OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/ALCOHOL POISONING
		1	31	15OCT2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/ALCOHOL POISONING
	C4591001 1071 10711216	1	4	12OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	SUBJECT HAD POSITIVE COVID TEST PRIOR TO VISIT 2. SUBJECT NO LONGER MEETS EXCLUSION #5
		1	123	08FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW UP
	C4591001 1072 10721043	2	177	10MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject moved to an assistant living facility
	C4591001 1072 10721044	2	160	22FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject received Moderna COVID-19 Vaccine
	C4591001 1072 10721062	2	160	22FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject received Moderna COVID-19 Vaccine
	C4591001 1072 10721065	1	22	18SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Withdrawal by subject
		1	22	18SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal by subject

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1073 10731023	2	149	20JAN2021	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject met exclusion #16 and inclusion #2 on 20January2021.
	C4591001 1073 10731030	2	155	27JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1073 10731037	2	149	22JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdrew Consent,subject no longer wants to be in the study.
	C4591001 1073 10731055	2	154	01FEB2021	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject moved out of state and withdrew consent. No longer interested.
	C4591001 1077 10771211	2	48	17NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject lost a parent to Covid-19 and stopped responding to site attempts to contact.
		2	48	17NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT LOST A PARENT TO COVID 19 AND STOPPED RESPONDING TO SITE ATTEMPTS TO CONTACT
	C4591001 1079 10791020	2	175	10FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Follow-up
	C4591001 1079 10791038	2	183	23FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrawn
	C4591001 1079 10791057	1	38	11SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject is lost to follow up
		1	38	11SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject is lost to follow up
	C4591001 1080 10801222			22SEP2020	FOLLOW-UP	OTHER	Subject was randomized but not vaccinated due to recruitment ending.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1081 10811149	2	120	19JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Moving out of state and does not want to continue in study nor transfer sites
	C4591001 1081 10811173	2	106	07JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subj. left vm with office stating to drop him from the study. subj. will not return calls to discuss
	C4591001 1082 10821029	2	1	25AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject completed vaccination 2 but did not complete the 1 month follow-up.
		2	29	22SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject completed vaccination 2 but did not complete the 1 month follow-up.
	C4591001 1082 10821062			06AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject was randomized but did not receive study vaccination. Subject left site prior to vaccination
	C4591001 1082 10821126	1	1	21AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent prior to receiving the second vaccination.
		1	33	22SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject did not complete follow-up period.
	C4591001 1082 10821164	1	25	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject believes that his first vaccine is what caused him to be COVID +.
		1	25	12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject believes that his first vaccine is what caused him to be COVID +.
	C4591001 1083 10831173	1	68	02NOV2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT
	C4591001 1083 10831220	2	99	05JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received COVID vaccine outside the study so they have to be dropped because Exclusion 12

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1083 10831230	2	157	05MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	WOC but also disclosed receipt of outside covid-19 vaccine
	C4591001 1083 10831239	2	98	05JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received non study covid-19 vaccine
	C4591001 1083 10831248	2	120	29JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received non-study coronavirus vaccination
	C4591001 1084 10841077	2	188	03MAR2021	OPEN LABEL TREATMENT	PROTOCOL DEVIATION	Subject received vaccine outside of study and moved out of state.
		2	188	03MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Received second Pfizer vaccine outside of study and moved to a different state
	C4591001 1084 10841078	2	142	14JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Received vaccine outside of study and withdrew consent
	C4591001 1084 10841158	2	130	11JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received vaccine outside of study
	C4591001 1084 10841180	2	53	26OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject dropped from trial
	C4591001 1084 10841184	2	53	26OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew from trial
		2	53	26OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew from trial
	C4591001 1084 10841198	2	119	05JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	received vaccine outside of study

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1084 10841245	2	104	23DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Received COVID-19 vaccine outside of study on 23Dec2020
	C4591001 1084 10841264	2	118	06JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received non-study COVID-19 vaccine
	C4591001 1084 10841266	2	121	12JAN2021	FOLLOW-UP	DEATH	DEATH/EMPHYSEMATOUS CHOLECYSTITIS
	C4591001 1084 10841366	2	121	12JAN2021	FOLLOW-UP	DEATH	DEATH/SEPSIS
	C4591001 1084 10841366			09SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject left during vaccine prep, was called and texted w/o response. Dropped from study.
	C4591001 1084 10841369	2	102	07JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal by subject
	C4591001 1084 10841446			25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew from trial
	C4591001 1084 10841470	2	83	11JAN2021	FOLLOW-UP	DEATH	DEATH/COVID-19
	C4591001 1084 10841476	2	86	28JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received non study Moderna outside of study
	C4591001 1084 10841505	2	55	06JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject informed our site that she was to get the Moderna vaccine on 06/jan/2021
	C4591001 1085 10851038	2	141	11JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrawal of Consent

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1085 10851040	2	195	09MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject moved out of state and closest site was 5 hours away. Subject decided to withdraw consent.
	C4591001 1085 10851071	2	185	04MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew consent
	C4591001 1085 10851080	2	119	04JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	COVID vaccine outside of the study.
	C4591001 1085 10851161	2	99	23DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew Consent
	C4591001 1085 10851218	2	133	02FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew Consent
	C4591001 1085 10851223	2	128	29JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent. Received COVID vaccine outside study.
	C4591001 1085 10851322	2	160	08MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew consent
	C4591001 1085 10851340	2	91	05JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew consent.
	C4591001 1087 10871080	1	44	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Withdrew consent d/t frustrations with limitations of double-blind study.
		1	44	24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew consent d/t frustrations with limitations of double-blind study.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1087 10871121	1	22	09SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/GASTROINTESTINAL HAEMORRHAGE
		1	22	09SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/GASTROINTESTINAL HAEMORRHAGE
	C4591001 1087 10871211	1	24	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Withdrawal of consent to participate in study due to not being able to get cash off of the ClinCard.
		1	24	17SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrawal of consent to participate in study due to not being able to get cash off of the ClinCard.
	C4591001 1087 10871228	1	22	16SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/CARDIAC FAILURE CONGESTIVE
		1	22	16SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/CARDIAC FAILURE CONGESTIVE
	C4591001 1087 10871269	2	154	23FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Received Moderna vaccine.
	C4591001 1087 10871270	2	154	23FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Received Moderna vaccine.
	C4591001 1087 10871347	2	146	23FEB2021	FOLLOW-UP	OTHER	Subject has moved out of State and is unable to return for Study procedures
	C4591001 1087 10871369	2	107	15JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	moved from area.
	C4591001 1087 10871425	2	153	01MAR2021	FOLLOW-UP	OTHER	Moving out of State

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1087 10871434			11SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt withdrew consent noting it would be very difficult to ever collect blood from her.
	C4591001 1087 10871505	1	23	13OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Pt reports she has a lot going on in her personal life & wishes to discontinue study.
		1	23	13OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt reports she has a lot going on in her life & wishes to discontinue study.
	C4591001 1087 10871512			22SEP2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject randomized in error
	C4591001 1087 10871560	1	91	12JAN2021	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
		1	91	12JAN2021	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1088 10881126	2	70	01DEC2020	FOLLOW-UP	DEATH	DEATH/CARDIAC ARREST
	C4591001 1088 10881139	2	143	06MAR2021	FOLLOW-UP	DEATH	DEATH/METASTASES TO LUNG
	C4591001 1089 10891073	2	70	12NOV2020	FOLLOW-UP	DEATH	DEATH/CHRONIC OBSTRUCTIVE PULMONARY DISEASE
	C4591001 1089 10891088	2	125	30DEC2020	FOLLOW-UP	DEATH	DEATH/DEMENTIA ALZHEIMER'S TYPE
	C4591001 1089 10891098	2	30	29SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject came by office an not longer wanted to do trial. returned diary

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		2	30	29SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject came by office an not longer wanted to do trial. returned diary
	C4591001 1089 10891118	2	174	22FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1089 10891191	2	98	22DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient withdrew consent
	C4591001 1089 10891344	1	35	26OCT2020	VACCINATION	LOST TO FOLLOW-UP	contacts attempted and certified letter sent
		1	35	26OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	several attempts have been made to contact subject and certified letter sent. LTFU
	C4591001 1090 10901087	2	142	16JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	pt wanted to be unblinded same day and could not wait until Monday
	C4591001 1090 10901119	2	141	18JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject wanted to be unblinded today and leave the study
	C4591001 1090 10901121	2	108	16DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	chose to received vaccine over her work
	C4591001 1090 10901141	2	9	08SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	pt is moving away and not able to come to visits any longer. He talked to PI
		2	9	08SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject moved away
	C4591001 1090 10901165	2	116	28DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject chooses to get vaccine over her employer today

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1090 10901342	2	125	03FEB2021	FOLLOW-UP	OTHER	pt moved away to a different state, no near research site available
	C4591001 1090 10901404	2	108	21JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Pfizer COVID vaccine over her work, without informing the site or being unblinded
	C4591001 1090 10901469	2	62	16DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject decided after unblinding to receive the vaccine over his work
	C4591001 1090 10901545	2	67	21JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	was unblinded, but will get vaccine outside of study
	C4591001 1091 10911092			10AUG2020	FOLLOW-UP	OTHER	subject randomized with incorrect subject demographics, was not dosed, then withdrawn and rescreened
	C4591001 1092 10921191	1	35	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not show for visit 2 unable to make contact with subject
		1	35	20OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not return for V2
	C4591001 1092 10921268	1	5	26OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject tested positive for COVID-19 with symptoms as noted in Illness visit.Meets EC #5
	C4591001 1093 10931050	1	24	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	PER PROTOCOL, PT WILL NOT RECEIVE SECOND VAX DUE TO POSITIVE COVID (SYMPTOMATIC), WILL STILL CONTINUE
	C4591001 1093 10931051	1	83	14NOV2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT WAS SENT A CERTIFIED LETTER AND WAS UNABLE TO BE CONTACTED MULTIPLE TIMES.
		1	83	14NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT WAS SENT A CERTIFIED LETTER AND WAS UNABLE TO BE CONTACTED MULTIPLE TIMES.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1093 10931060	2	148	09FEB2021	REPEAT SCREENING 1	OTHER	SUBJECT WAS DELAYED DUE TO BEING MEDICALLY UNSTABLE.
	C4591001 1093 10931159	2	120	08FEB2021	FOLLOW-UP	OTHER	SUBJECT DOES NOT WANT TO CONTINUE WITH VACCINATION AT THIS TIME.
	C4591001 1093 10931191	1	105	02FEB2021	VACCINATION	OTHER	ONLY RX WAS DELAYED. SUBJECT PROCEEDED TO OPEN LABEL VISIT PRIOR TO ATTENDING THEIR V2.
	C4591001 1094 10941021	2	170	24FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal of consent
	C4591001 1094 10941027	2	161	15FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received the non study covid 19 vaccine before being discontinued or withdrawing from study
	C4591001 1094 10941044	2	164	24FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal of consent
	C4591001 1094 10941054	2	161	22FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received the non study covid 19 vaccine before being discontinued or withdrawing from study
	C4591001 1094 10941080	1	24	25SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrawal of consent by subject
		1	24	25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal of consent by patient
	C4591001 1094 10941112	2	81	18DEC2020	FOLLOW-UP	DEATH	DEATH/ACUTE RESPIRATORY FAILURE

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1094 10941114	2	147	22FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawn consent due to time commitment
	C4591001 1094 10941130	1	32	16OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		1	32	16OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1094 10941191†	1	1	30OCT2020	SCREENING	SCREEN FAILURE	SCREEN FAILURE
	C4591001 1095 10951077	2	182	24FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	COVID-19 vaccine received outside of study.
	C4591001 1095 10951102	1	35	10SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Unwilling to come back for appt at this time. Participant did not verbalize withdrawing consent
		1	35	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Unwilling to come back for appt at this time. Participant did not verbalize withdrawing consent
	C4591001 1095 10951139	2	178	12MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Participant reported receipt of vaccine outside of study
	C4591001 1096 10961048	1	28	14SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrew consent
		1	28	14SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrew consent
	C4591001 1096 10961082	1	54	12OCT2020	VACCINATION	LOST TO FOLLOW-UP	LTFU, unresponsive to contact attempts

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	54	12OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	site unable to contact subject after multiple attempts and certified letter sent
	C4591001 1096 10961086	1	52	11OCT2020	VACCINATION	LOST TO FOLLOW-UP	LTFU, unresponsive to contact attempts
		1	52	11OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	LTFU, unresponsive to contact attempts
	C4591001 1096 10961160	1	47	13OCT2020	VACCINATION	LOST TO FOLLOW-UP	unable to reach subject despite numerous attempt and certified letter was sent
		1	47	13OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	unable to reach subject despite numerous attempt and certified letter was sent
	C4591001 1096 10961234	2	99	31DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received COVID vaccine outside of trial
	C4591001 1096 10961292	2	101	06JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	covid-19 vaccination outside of study
	C4591001 1096 10961371	2	83	16JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Covid-19 vaccination outside of study
	C4591001 1097 10971003			19AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Randomized in error.
	C4591001 1097 10971023	2	98	21DEC2020	FOLLOW-UP	DEATH	DEATH/SEPTIC SHOCK
	C4591001 1097 10971033	1	23	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Patient decided that he no longer wanted to be involved in the trial.
		1	23	16SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt decided that he no longer wanted to be involved in the trial.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1098 10981008	2	169	24FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Moderna Covid-19 vaccine
	C4591001 1098 10981026	2	33	26OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject no longer wanted to participate in the study.
		2	33	26OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	no reason given.
	C4591001 1098 10981030	1	17	06SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject Withdraw consent and no longer interested in participating in research trial.
		1	17	06SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent because he believed site has infected him with Covid-19 .
	C4591001 1098 10981092			03SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawl
	C4591001 1098 10981109			04SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject unable to be compliant and comit to schedule visitand vaccination plans.
	C4591001 1098 10981119	2	103	04JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	discontinued
	C4591001 1098 10981130	2	30	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew the consent , as he was will be not able to be compliant in the future.
		2	30	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew the consent , as he was will be not able to be compliant in the future.
	C4591001 1098 10981201	2	95	14JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject got Pfizer Vaccine for Covid-19 on 05-Jan-2020.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1098 10981203	2	85	04JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject is excluded from the study as the subject received the Moderna vaccine.
	C4591001 1098 10981212	2	94	14JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Discontinued due to receiving non-study Covid Vaccine.
	C4591001 1098 10981227	2	97	19JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	subject got Moderna vaccine 1st dose on 19-Jan-2021.
	C4591001 1098 10981237	2	108	04FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Non-Pfizer Covid Vaccine
	C4591001 1098 10981250	2	69	05JAN2021	VACCINATION	LOST TO FOLLOW-UP	unable to get hold of subject
		2	69	05JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	unable to get hold of pt.
	C4591001 1101 11011066	2	103	18JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject opted to crossover, but was not able to come for vaccination 3 and 4 due to her job
	C4591001 1107 11071024	2	183	24FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECIEVED MODERNA VACCINE
	C4591001 1107 11071103	2	141	20JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT. HE DID NOT WANT TO RECEIVE THE VACCINE.
	C4591001 1109 11091051	2	137	04JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject was unblinded by own request not eligible for unblinding by EUA
	C4591001 1109 11091093	2	45	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject never return for visit, returned call or returned certified letter.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		2	45	07OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject never return for visit, returned call or returned certified letter.
	C4591001 1109 11091095	2	37	29SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject called site and withdrew consent today.
		2	37	29SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject called site and withdrew consent today.
	C4591001 1109 11091248	1	25	09SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT CALLED WHEN V-2 WAS MISSED AND SHE STATED NO LONGER WANTING TO PARTICIPATE.
		1	25	09SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT CALLED WHEN V-2 WAS MISSED AND SHE STATED NO LONGER WANTING TO PARTICIPATE.
	C4591001 1109 11091253	2	46	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO MULTIPLE CALLS AND CERTIFIED LETTER SENT
		2	46	20OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO MULTIPLE CALLS AND CERTIFIED LETTER SENT
	C4591001 1109 11091259			16AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Randomized in error
	C4591001 1109 11091346	2	170	05MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	No longer wanted to participate
	C4591001 1109 11091363	2	113	14JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wanted to continue with study.
	C4591001 1109 11091411	2	146	18FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wants to participate and want to get the vaccine else where.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1109 11091475	1	51	29OCT2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO CALLS OR CERTIFIED LETTER
		1	51	29OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO CALLS OR CERTIFIED LETTER
	C4591001 1109 11091503	1	20	30SEP2020	VACCINATION	ADVERSE EVENT	Subject declined second vaccine however is willing to continue followup if approved by sponsor./ABDOMINAL PAIN UPPER
	C4591001 1109 11091510	2	102	13JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wanted to participate
	C4591001 1110 11101239	2	72	15DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject wants to be discontinued from the study because he can not comply with the study schedule
	C4591001 1110 11101241	1	95	17DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject state he do not want to continued in the study
		1	95	17DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject wants to be discontinued from the study because he can not comply with the study schedule
	C4591001 1111 11111063	2	130	04JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Moderna COVID-19 vaccine outside of study
	C4591001 1111 11111065	2	109	17DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject received vaccine outside of study
	C4591001 1111 11111095	2	98	07DEC2020	VACCINATION	LOST TO FOLLOW-UP	Subject has not responded back to us after multiple contact attempts
		2	98	07DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject has not responded back to us after multiple contact attempts

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1111 11111110	2	124	05JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject chose to get vaccine outside of study
	C4591001 1111 11111112	2	32	05OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent verbally due to no longer wanting to participate
		2	32	05OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrawal
	C4591001 1111 11111206	2	41	21DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received COVID-19 vaccination outside of study and is no longer in the study.
	C4591001 1112 11121052	1	50	22SEP2020	VACCINATION	LOST TO FOLLOW-UP	unable to reach subject for follow up visits
		1	50	22SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	unable to reach subject to return for follow up visits
	C4591001 1112 11121118	1	2	12AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/TACHYCARDIA
	C4591001 1112 11121134	1	38	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject no longer wishes to continue
		1	38	24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject does not wish to continue in study
	C4591001 1112 11121255	1	2	07OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/CHILLS
		1	2	07OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/HEADACHE
		1	2	07OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/PYREXIA

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1112 11121337	1	6	26OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DIARRHOEA
		1	23	12NOV2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/FATIGUE
	C4591001 1114 11141050	2	42	19OCT2020	FOLLOW-UP	DEATH	DEATH/SUDDEN CARDIAC DEATH
	C4591001 1114 11141102	2	101	23DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Covid vaccine before unblinding
	C4591001 1114 11141120	2	109	14JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject Received vaccine outside of study
	C4591001 1116 11161117			03SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	ICF Withdrawn
	C4591001 1116 11161118			03SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	ICF Withdrawn
	C4591001 1116 11161151	2	124	29JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject was unblinded and offered the vaccine, patient declined the vaccine, and withdrew from study
	C4591001 1116 11161246	2	121	05FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Husband of subject is in hospice, she could not continue in the study
	C4591001 1116 11161253	1	11	28SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Patient was symptomatic and tested positive for COVID-19 between Vaccine 1 and Vaccine 2
		1	134	29JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received outside EAU vaccine

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1116 11161291	2	85	06JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject sent letter to site dated 06Jan2021 requesting to withdraw from the trial
	C4591001 1116 11161328	2	72	07JAN2021	VACCINATION	LOST TO FOLLOW-UP	Dec29, Jan7, Jan7, Jan19
		2	90	25JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	12Dec2020, 7Jan2021,7Jan2021, 19Jan2021, 22Jan2021
	C4591001 1117 11171114	2	73	18DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	RECEIVED COVID VACCINE OUTSIDE OF STUDY
	C4591001 1118 11181065	1	50	07OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent prior to coming in for visit 2 after visit 2 was missed multiple times
		1	50	07OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject missed visit 2 appointment and has not returned any contact attempts from the site.
	C4591001 1118 11181090	2	21	05OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrew consent
		2	21	05OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	WITHDREW CONSENT
	C4591001 1118 11181124	2	86	05FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received Moderna COVID-19 vaccine outside of study - withdrawn from study
	C4591001 1120 11201007	2	175	09FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject moved out of state
	C4591001 1120 11201050	2	73	07NOV2020	FOLLOW-UP	DEATH	DEATH/CARDIAC ARREST

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1120 11201066	1	66	09OCT2020	VACCINATION	LOST TO FOLLOW-UP	UNABLE TO BE REACHED FOR VISIT 2
		1	66	09OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject phone disconnected emergency contact can't be reached and certified letter sent no response
	C4591001 1120 11201073	1	24	28AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject refused vax 2. will follow subject throughout duration of study
		1	203	23FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdraw consent
	C4591001 1120 11201080	2	165	04FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject moved out of town and wanted to withdraw from study.
	C4591001 1120 11201127	1	4	14AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DIARRHOEA
		1	4	14AUG2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/DIARRHOEA
	C4591001 1120 11201134	2	167	15FEB2021	FOLLOW-UP	OTHER	subject took a job out of state
	C4591001 1120 11201164	2	166	15FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Moderna Covid-19 Vaccine
	C4591001 1120 11201182	2	37	09OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject stated he wanted to withdraw
		2	37	09OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject stated he wanted to withdraw
	C4591001 1120 11201243	2	162	18FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDRAW

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1120 11201317	2	109	22FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received moderna COVID vaccine
	C4591001 1120 11201335	1	11	26OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5 VAX2 is not given but FUP will be completed
	C4591001 1120 11201351	1	22	10NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject DOES NOT WISH TO RECEIVE VAX 2
	C4591001 1120 11201436			30OCT2020	VACCINATION	OTHER	Subject was discontinued
				30OCT2020	FOLLOW-UP	OTHER	discontinued
	C4591001 1121 11211019	2	131	22JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Due to lack of IP availability at site. Needs vaccine for work
	C4591001 1121 11211021	2	168	02MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject contacted site and requested to be withdrawn from the trial
	C4591001 1121 11211031	2	155	19FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew to receive vaccine elsewhere
	C4591001 1121 11211047	2	138	04FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Due to vaccine availability today. receiving off site this afternoon.
	C4591001 1121 11211051	2	133	01FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Due to receiving vaccine sooner outside of site.
	C4591001 1121 11211072	2	120	19JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew to receive vaccination elsewhere

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1121 11211092	2	121	26JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject had the opportunity to receive vaccine. Subject withdrew consent.
	C4591001 1121 11211104	2	101	08JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew to receive vaccine at work
	C4591001 1121 11211119	2	128	04FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject can no longer wait to receive vaccine
	C4591001 1121 11211122	2	107	14JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Does not want to wait to receive vaccine on site
	C4591001 1123 11231193	2	94	23DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	subject received non-study covid-19 vaccine
	C4591001 1123 11231214	2	136	05FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	received non-study vaccine
	C4591001 1123 11231244	2	102	14JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received non-study vaccination
	C4591001 1123 11231273	2	105	19JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Received non-study vaccine
	C4591001 1124 11241015	2	190	08MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	received moderna vaccine outside of study
	C4591001 1124 11241079	2	178	04MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject did not come in and requested to be dropped from the study.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1124 11241140	2	145	15FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Moderna vaccine outside of study
	C4591001 1125 11251072	2	167	22FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	wishes to get vaccine elsewhere
	C4591001 1125 11251107	2	116	12FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient withdrew consent
	C4591001 1125 11251157	2	157	28FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient withdrew consent
	C4591001 1125 11251196	2	148	25FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient was contacted for Initial contact and wished to with draw form study
	C4591001 1125 11251211	1	5	15SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	did not receive 2nd vax no longer meets Exclusion #5
	C4591001 1125 11251227	2	100	25FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject planned to receive vaccine elsewhere. Subject withdrew consent prior to receiving other vax.
	C4591001 1125 11251230	2	51	29DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient no longer wishes to participate in the study
	C4591001 1126 11261147	2	120	28JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Received Covid 19 Vaccine outside of study, manufacturer UNNOWN. Date: UNK/UNK/2021
	C4591001 1127 11271009	2	156	20JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	subject was vaccinated with COVID19 vaccine outside study.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1127 11271041	2	154	21JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	subject vaccinated outside of study
	C4591001 1127 11271051	2	122	23DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Discontinued. Subject vaccinated outside of study
	C4591001 1127 11271089	2	144	20JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	subject vaccinated with another COVID19 vaccine outside study
	C4591001 1127 11271098	2	115	31DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject vaccinated outside of study
	C4591001 1128 11281009	2	102	28NOV2020	FOLLOW-UP	DEATH	DEATH/PNEUMONIA
	C4591001 1128 11281010	2	143	08JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	DROPPED-SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY
	C4591001 1128 11281023			01AUG2020	FOLLOW-UP	OTHER	unable to obtain lab sample, therefore subject was discontinued
	C4591001 1128 11281036	2	117	18DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	DROPPED-SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY
	C4591001 1128 11281079	2	144	18JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	DROPPED-SUBJECT GOT COVID-19 VACCINE OUTSIDE OF STUDY
	C4591001 1128 11281109			12AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject changed his mind regarding participation in the Covid clinical trial

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1128 11281185	2	125	18JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	DROPPED-SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY
	C4591001 1128 11281212	2	33	19OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
		2	33	19OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT TO PROCEED IN STUDY
	C4591001 1128 11281335	2	111	18JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	DROPPED-SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY
	C4591001 1128 11281360	2	155	09MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject wishes to withdraw from study
	C4591001 1129 11291037	2	177	16FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Non-study Moderna Covid-19 Vaccination
	C4591001 1129 11291082			10AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	screen fail
				10AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	randomized but not dosed. failed exclusion criteria g. bleeding condition
	C4591001 1129 11291117			17AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	screen fail
				17AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	failed exclusion criteria L. - participation in other studies. randomized but not dosed
	C4591001 1129 11291166	2	129	03FEB2021	FOLLOW-UP	DEATH	DEATH/MYOCARDIAL INFARCTION

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1129 11291174	2	101	13JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received Covid-19 vaccination outside of the trial.
	C4591001 1131 11311145	1	91	07DEC2020	VACCINATION	LOST TO FOLLOW-UP	Subject has not reached out to site after repeated attempts. Certified letter delivered 07DEC2020
		1	91	07DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject has not reached out to site after repeated attempts. Certified letter delivered 07DEC2020
	C4591001 1131 11311204	2	124	15FEB2021	OPEN LABEL TREATMENT	DEATH	DEATH/CARDIO-RESPIRATORY ARREST
		2	124	15FEB2021	FOLLOW-UP	DEATH	DEATH/CARDIO-RESPIRATORY ARREST
	C4591001 1133 11331012	2	96	24NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject has been non-compliant with diary. Certified letter sent
	C4591001 1133 11331080	2	49	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		2	49	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1133 11331089	2	115	21DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject recieved the Covid-19 vaccine outside the study(at work)
	C4591001 1133 11331104	2	129	04JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received COVID-19 Vaccine on 28/DEC/20
	C4591001 1133 11331136	2	151	01FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent on 16/DEC/2020

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1133 11331168	2	34	07OCT2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
		2	34	07OCT2020	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1133 11331174	2	57	30OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject refuse to be compliant with diary. He is not longer interesting in study.
	C4591001 1133 11331179	2	118	30DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent due to personal reasons
	C4591001 1133 11331191	2	113	30DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent due to personal reasons
	C4591001 1133 11331197			19AUG2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	subject received shingle vaccine on 7/22/2020, subject was not dosed
	C4591001 1133 11331223	2	114	07JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent 02/DEC/2020.
	C4591001 1133 11331304	2	119	14JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT WAS VACCINATED WITH PFIZER VACCINE IN DEC/JAN
	C4591001 1133 11331314	2	121	28JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject received covid vaccine at work. Subject can remain but subject withdraws consent
	C4591001 1133 11331318	2	95	21DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT 20NOV. SUBJECT NEVER ANSWERED BACK.
	C4591001 1133 11331384	2	169	10MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent 26/FEB/2021

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1133 11331424	2	97	04JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received COVID-19 Vaccine (Moderna)
	C4591001 1133 11331425	2	97	04JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Moderna Covid-19 on 12/31/20 Vaccine
	C4591001 1133 11331426	1	34	12OCT2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT IS LTF. CERTIFIED LETTER SENT 12/OCT/20
		1	34	12OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT IS LTF. CERTIFIED LETTER SENT 12/OCT/20
	C4591001 1133 11331452	2	118	03FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent 11/DEC/2020
	C4591001 1133 11331472	1	33	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	Unable to contact subject
		1	33	20OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Unable to contact subject
	C4591001 1133 11331481	1	24	14OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject doesn't feels comfortable receiving the second vaccine.
		1	24	14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject does not feel comfortable receiving 2nd vaccine and withdrew consent from follow up as well
	C4591001 1133 11331507	2	136	26FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT 19/FEB/21
	C4591001 1134 11341019	2	156	02FEB2021	OPEN LABEL TREATMENT	ADVERSE EVENT	ADVERSE EVENT/ANGINA PECTORIS

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1134 11341069	2	134	12JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	DROPPED
	C4591001 1134 11341073	2	146	27JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECEIVED COVID VACCINE OUTSIDE THE STUDY.
	C4591001 1134 11341130			20AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1134 11341206	2	133	28JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECEIVED A COVID VACCINE OUTSIDE OF THE STUDY.
	C4591001 1135 11351033	2	156	29JAN2021	OPEN LABEL TREATMENT	DEATH	DEATH/COMPLETED SUICIDE
	C4591001 1135 11351092	2	156	29JAN2021	FOLLOW-UP	DEATH	DEATH/COMPLETED SUICIDE
	C4591001 1135 11351092	2	122	30DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	subject was withdrawn from study
	C4591001 1135 11351131	2	93	02DEC2020	FOLLOW-UP	OTHER	subject dropped from study due to non-compliance
	C4591001 1135 11351236	2	150	18FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew from study
	C4591001 1136 11361102	2	31	19DEC2020	VACCINATION	DEATH	DEATH/CARDIAC ARREST
		2	31	19DEC2020	FOLLOW-UP	DEATH	DEATH/CARDIAC ARREST

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1139 11391057	2	141	13JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject wanted to get vaccine at their Primary Care Visit outside of study.
	C4591001 1139 11391096	2	58	23DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject needed to be unblinded and will receive vaccine at their current rehab facility
	C4591001 1139 11391097	2	85	21JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject decided to receive vaccine elsewhere after being unblinded
	C4591001 1140 11401002	2	32	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject no longer wanted to participate after experiencing a spontaneous coronary artery dissection
		2	32	17SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wanted to participate after experiencing a spontaneous coronary artery dissection
	C4591001 1140 11401003	2	32	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Not interested in remaining in study
		2	32	17SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject not interested in continuing. Have been unable to reach to have come in for follow up
	C4591001 1140 11401035	1	50	22SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/URTICARIA
		1	50	22SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/URTICARIA
	C4591001 1140 11401117	2	117	29DEC2020	FOLLOW-UP	DEATH	DEATH/CARDIAC ARREST
	C4591001 1140 11401172	2	118	05JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject withdrawn due to receiving the COVID vaccine elsewhere outside of the study

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1140 11401191	2	135	26JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject received vaccine outside of study and withdrew their consent
	C4591001 1141 11411009	2	120	16DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent.
	C4591001 1141 11411101	2	131	19JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrew to receive EUA outside of study
	C4591001 1141 11411225	2	82	29DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent.
	C4591001 1145 11451014	2	155	03FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	volunteer received vaccine outside of study treatment
	C4591001 1145 11451041	2	49	02NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	volunteer withdrawn no longer wants to be part of study.
		2	49	02NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	volunteer refuses to come for additional visits.
	C4591001 1145 11451076	1	18	21SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/PARKINSONISM
	C4591001 1146 11461175	2	147	14FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew.
	C4591001 1146 11461214	2	145	14FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1146 11461215	2	163	05MAR2021	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	subject enrolled in another clinical trial so no longer eligible.
	C4591001 1147 11471023	2	149	19JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Non-study COVID-19 Vaccine (Moderna)
	C4591001 1147 11471036	2	141	12JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received COVID-19 vaccination outside of study
	C4591001 1147 11471117	2	125	05JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received COVID-19 vaccine outside of study
	C4591001 1149 11491100			20AUG2020	VACCINATION	REFUSED FURTHER STUDY PROCEDURES	REFUSED FURTHER STUDY PROCEDURES
				20AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew prior to vaccination
	C4591001 1149 11491105	2	61	09NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject is non responsive. Certified letter sent 30OCT2020.
		2	61	09NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is non responsive. Certified letter sent 30OCT2020.
	C4591001 1149 11491126	1	71	30OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject was mailed certified letter 30OCT2020.
		1	71	30OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Certified Letter sent 30OCT2020
	C4591001 1149 11491224	1	61	09NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject is non responsive. Certified letter sent 30OCT2020.
		1	61	09NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is non responsive. Certified letter sent 30OCT2020.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1152 11521099	2	148	04FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECEIVED OTHER COVID VACCINE OUTSIDE OF THE STUDY.
	C4591001 1152 11521425	2	164	10MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Received alternative COVID-19 Vaccine, withdrawn from study.
	C4591001 1152 11521476	1	21	15OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DEAFNESS UNILATERAL
	C4591001 1152 11521497	1	36	11NOV2020	VACCINATION	DEATH	DEATH/SHIGELLA SEPSIS
		1	36	11NOV2020	FOLLOW-UP	DEATH	DEATH/SHIGELLA SEPSIS
	C4591001 1156 11561044	1	13	08SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	EXCLUSION CRITERIA #5
	C4591001 1156 11561140	2	155	08MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	WITHDRAWAL OF CONSENT
	C4591001 1156 11561160†	2	74	24DEC2020	FOLLOW-UP	DEATH	DEATH/ROAD TRAFFIC ACCIDENT
	C4591001 1157 11571028			17AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject could not make future study appointments
	C4591001 1157 11571039	2	184	12MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject contacted site and withdrew consent
	C4591001 1157 11571068	2	146	01FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject dropped not due to an AE or SAE.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1157 11571069	2	125	18JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of COVID vaccine outside of trial
	C4591001 1157 11571119	2	110	15JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject had imminent access to Pfizer vaccine outside of study.
	C4591001 1157 11571131	1	156	04FEB2021	VACCINATION	WITHDRAWAL BY SUBJECT	Voluntary withdrawal not due to an adverse event
		1	156	04FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Voluntary withdrawal not due to an AE or SAE
	C4591001 1157 11571161	2	82	29JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received the Moderna COVID vaccine
	C4591001 1162 11621022	2	155	28JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
	C4591001 1162 11621065	2	189	09MAR2021	OPEN LABEL TREATMENT	LOST TO FOLLOW-UP	LTFU
		2	189	09MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	subject has not returned to site for V102
	C4591001 1162 11621167	2	121	14JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent after unblinding
	C4591001 1162 11621280	2	36	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		2	36	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1162 11621281	2	155	25FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT; RECEIVED VACCINE ELSEWHERE
	C4591001 1162 11621327	1	4	13SEP2020	VACCINATION	DEATH	Cause of Death Atherosclerotic Disease/ARTERIOSCLEROSIS
		1	4	13SEP2020	FOLLOW-UP	DEATH	DEATH/ARTERIOSCLEROSIS
	C4591001 1162 11621349	1	58	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU after many contact attempts
		1	58	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU after many contact attempts
	C4591001 1162 11621407	1	51	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject Lost to Follow-Up after many attempts to contact.
		1	51	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject Lost to Follow-Up after many attempts to contact.
	C4591001 1163 11631005	1	20	19AUG2020	VACCINATION	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT/PRODUCT ADMINISTRATION ERROR
		1	195	10FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	WITHDRAWAL BY SUBJECT/PRODUCT ADMINISTRATION ERROR
	C4591001 1163 11631008	1	21	20AUG2020	VACCINATION	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT/PRODUCT ADMINISTRATION ERROR
	C4591001 1163 11631030	2	192	03MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Going to get outside vaccination in Houston Texas/DRUG THERAPY
	C4591001 1163 11631041	2	123	28DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	OUTSIDE VAX

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1163 11631100	1	150	08JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Planned non-study vaccine receipt
	C4591001 1166 11661001	2	142	28JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT UNBLINDED VIA FORM 1 AND WITHDREW CONSENT THEREAFTER. WANTED VAX OUT OF STUDY.
	C4591001 1166 11661013	2	149	05FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	WITHDRAWAL OF CONESNT. RECEIVED MODERNA VAX OFF-STUDY.
	C4591001 1166 11661105	2	31	18DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WANTED TO RECEIVE VACCINE OUT OF STUDY AND THUS WITHDREW CONSENT.
		2	31	18DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	WITHDREW CONSENT PRIOR TO VACCINATION.
	C4591001 1168 11681012	2	29	01OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	patient withdrew consent
		2	29	01OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient withdrew consent
	C4591001 1168 11681015	1	21	02SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Patient withdrew consent
		1	21	02SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient withdrew consent
	C4591001 1168 11681083	2	65	18NOV2020	FOLLOW-UP	DEATH	DEATH/AORTIC RUPTURE
	C4591001 1168 11681180	2	140	23FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal by subject

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1169 11691045	2	78	22DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received covid vaccine outside of the study prior to unblinding- withdrawn from study
	C4591001 1170 11701033	2	167	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1170 11701113	2	131	26JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject got vaccine from elsewhere
	C4591001 1170 11701173	2	98	29DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject decided to get vaccine with PCP
	C4591001 1170 11701188	2	154	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1170 11701224	2	120	26JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	received vaccine outside of study
	C4591001 1170 11701328	2	41	16NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject no longer wants to participate in the trial. Documentation can be found in Florence.
		2	65	10DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wants to participate in the trial.
	C4591001 1170 11701354	1	29	16OCT2020	VACCINATION	OTHER	subject was initially lost to follow up but rejoined the study to receive vaccination 3
		1	137	01FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject got unblinding status and withdrew again
	C4591001 1171 11711132	2	178	12MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received MRNA 1273 outside of the study

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1174 11741041	2	35	03NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject withdrew from the trial before completing visit three for a personal reason
		2	35	03NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject has withdrawn from the study overall
	C4591001 1177 11771476	2	98	10FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Previous vaccination with non-Pfizer COVID-19 vaccine
	C4591001 1178 11781046	2	92	21DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject asked to be withdrawn from study and IRB notified. Please review documents in Florence.
	C4591001 1178 11781056			31AUG2020	VACCINATION	PROTOCOL DEVIATION	Subject randomized in error.
				31AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	subject randomized in error
	C4591001 1178 11781060	2	116	15JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Moderna vaccine from outside source.
		2	116	15JAN2021	REPEAT SCREENING 1	NO LONGER MEETS ELIGIBILITY CRITERIA	Patient received Moderna Vaccine at outside facility.
	C4591001 1178 11781068	2	107	06JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Patient received Pfizer Covid-19 Vaccine through health department.
	C4591001 1178 11781282	2	74	07JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject is withdrawing from study to receive vaccine elsewhere. See progress notes.
		2	74	07JAN2021	REPEAT SCREENING 1	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject withdrew from study to receive outside vaccine.
	C4591001 1178 11781315	2	66	15JAN2021	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	Withdrawn from study for noncompliance.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		2	66	15JAN2021	REPEAT SCREENING 1	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject was withdrawn by PI due to noncompliance
	C4591001 1179 11791065	2	45	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	Despite repeated attempts to contact subject to scheduled V3 subject has not replied by final notice
		2	45	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Despite repeated attempts to contact subject to scheduled V3 subject has not replied by final notice
	C4591001 1179 11791169	1	20	18NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1185 11851006			27OCT2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	discontinued
	C4591001 1194 11941037	2	48	22DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Possibility of regular vaccination was given
	C4591001 1203 12031013	2	65	12JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	unblinding due to vaccination against Covid19 outside the study centre
	C4591001 1204 12041002	2	148	08FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt unblinded Feb 8 2021 and declined vaccine administration and requested withdrawal from study
	C4591001 1204 12041057	1	59	05NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew from the study.
	C4591001 1204 12041117	2	91	07JAN2021	VACCINATION	PROTOCOL DEVIATION	1117 missed 1 month visit since they were not in the country & transfer took long time to process.
	C4591001 1207 12071055	2	76	09FEB2021	FOLLOW-UP	DEATH	DEATH/PNEUMONIA BACTERIAL

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1213 12131021	2	88	19FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawl cosent for no any further contact with subject
	C4591001 1213 12131023	1	8	10NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criteria 5
	C4591001 1213 12131029	2	88	20FEB2021	VACCINATION	WITHDRAWAL BY SUBJECT	withdrawl consent for no any further contact With subject
		2	94	26FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawl cosent for no any further contact with subject
	C4591001 1214 12141011	1	24	19NOV2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
		1	24	19NOV2020	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1218 12181020	2	17	18DEC2020	VACCINATION	OTHER	Subject proceeded to open label prior to V3 in the blinded Rx phase.
	C4591001 1219 12191032	2	21	22DEC2020	VACCINATION	OTHER	subject proceeded to open label prior to visit 3
	C4591001 1219 12191038	2	35	12JAN2021	VACCINATION	WITHDRAWAL BY SUBJECT	study participant received vaccination at the local hospital
	C4591001 1219 12191052	1	22	23DEC2020	VACCINATION	OTHER	subject proceeded to open label prior to vax 2 in the blinded treatment phase
	C4591001 1219 12191055	1	20	22DEC2020	VACCINATION	OTHER	subject proceeded to open label prior to Vax 2 in the blinded treatment phase.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1219 12191060	1	22	29DEC2020	VACCINATION	OTHER	subject proceeded to open label prior to vax 2 in the blinded treatment phase
	C4591001 1220 12201034	2	24	16DEC2020	VACCINATION	OTHER	Emergency use authorization of Pfizer COVID vaccine for healthcare workers
	C4591001 1220 12201055	2	7	17DEC2020	VACCINATION	OTHER	Participant was unblinded for EUA of COVID vaccine for healthcare workers.
	C4591001 1221 12211027	2	24	17DEC2020	VACCINATION	OTHER	Cross over to V101
	C4591001 1221 12211057	2	4	17DEC2020	VACCINATION	OTHER	Cross over to V101
	C4591001 1221 12211084	2	15	11JAN2021	VACCINATION	OTHER	Cross over to V101
	C4591001 1221 12211085	1	17	23DEC2020	VACCINATION	OTHER	Cross over to V101 prior to V2
	C4591001 1221 12211092	2	11	07JAN2021	VACCINATION	OTHER	Cross over to V101
	C4591001 1223 12231159	2	36	05NOV2020	VACCINATION	OTHER	patient had medical condition which precluded her from coming to visit 3
	C4591001 1223 12231215			30SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject left after signing consent, before dosing and did not return.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1223 12231250			16OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject changed his mind.
	C4591001 1224 12241033	2	37	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Dissatisfied with trial procedures.
	C4591001 1224 12241157			16SEP2020	FOLLOW-UP	PROTOCOL DEVIATION	PT is dialysis recipient; screen failure determined by study team during V1. PT discontinued
	C4591001 1226 12261381	2	80	02DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject do not want to continue in the study.
	C4591001 1226 12261613	1	22	28SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Patient chose not to take the second dose of the vaccine. Continue to the next visit
		1	159	12FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Although the patient received the 1st dose of placebo, she chose not to take the vaccine for fear.
	C4591001 1226 12262240	1	41	25NOV2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1229 12291041	1	35	02NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject is no longer interested in being part of the study.
		1	35	02NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject is no longer interested in being part of the study.
	C4591001 1231 12311132	2	150	29JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	The subject was administered the Gam-COVID-Vac vaccine (trade name Sputnik V)
	C4591001 1231 12311181	2	156	04FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	personal reasons

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12311329	2	39	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject asked to be withdrawn from the study due to aggravation of chronic lower back pain.
		2	39	12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject asked to be withdrawn from the study due to aggravation of chronic lower back pain.
	C4591001 1231 12311379	2	171	24FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	The volunteer was given a vaccine not related to the study
	C4591001 1231 12311400	2	48	21OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The volunteer signed up to participate in another study.
		2	48	21OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The volunteer signed up to participate in another study.
	C4591001 1231 12311549	1	37	21SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311723	1	23	08SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311810	2	31	07OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subjects affirms that the desition to stop participating in the study is personal
		2	31	07OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subjects affirms that the desition to stop participating in the study is personal
	C4591001 1231 12311815	1	21	06SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/LYMPHOPROLIFERATIVE DISORDER
	C4591001 1231 12311855	2	179	04MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	the participant reports having applied the ChAdOx1nCoV-19 vaccine (trade name COVISHIELD

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12311935	1	22	08SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19.
	C4591001 1231 12312058	2	43	29OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to family reasons.
		2	43	29OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to family reasons.
	C4591001 1231 12312130	1	38	24SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312222			19AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject randomized in error
	C4591001 1231 12312530	2	19	28SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the volunteer refers that the decision to stop participating is due to personal reasons
		2	19	28SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the volunteer refers that the decision to stop participating is due to personal reasons
	C4591001 1231 12312571	1	28	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312855	2	26	04OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is for personal reasons
		2	26	04OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is for personal reasons
	C4591001 1231 12313003	1	20	09SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The volunteer states that the decision to stop participating in the study is of a personal nature.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	20	09SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The volunteer states that the decision to stop participating in the study is of a personal nature.
	C4591001 1231 12313039	1	29	19SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
		1	29	19SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
	C4591001 1231 12313090	1	46	06OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313103	1	31	21SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313346	2	174	07MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	participant reports having applied the Gam-COVID-Vac vaccine (trade name Sputnik V)
	C4591001 1231 12313391	2	84	30DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject received the first dose of the Gam-COVID-vac (Sputnik V) vaccine
	C4591001 1231 12313457	1	33	24SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313461	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject declined to receive second vaccination but wishes to continue in the study
	C4591001 1231 12313468	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject decides not to take the 2nd dose of the research product, and continues in follow-up
	C4591001 1231 12313478	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject explained that he didn't want to receive the second dose of investigation product

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12313480	1	25	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not want to receive a second dose but did continue in the study
	C4591001 1231 12313538	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not agree to be vaccinated a second time, but will continue in the study
	C4591001 1231 12313621	2	42	26OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons
		2	42	26OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons
	C4591001 1231 12313651	1	22	14SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313740	2	55	07NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject stops participating in the study due to emigration to another country.
		2	55	07NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject stops participating in the study due to emigration to another country.
	C4591001 1231 12313972	2	16	28SEP2020	VACCINATION	DEATH	DEATH/HAEMORRHAGIC STROKE
		2	16	28SEP2020	FOLLOW-UP	DEATH	DEATH/HAEMORRHAGIC STROKE
	C4591001 1231 12314003	2	30	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons
		2	30	12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons
	C4591001 1231 12314060	1	57	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not reply to the registered letter. Contact is considered lost.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	57	20OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not reply to the registered letter. Contact is considered lost.
	C4591001 1231 12314120	1	20	14SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	did not agree that the Visit 1 swab result had not been given
		1	20	14SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	did not agree that the Visit 1 swab result had not been given
	C4591001 1231 12314189	1	20	14SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject misunderstood protocol and/or consent. Revokes consent.
		1	20	14SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	DISCONTINUED
	C4591001 1231 12314216	1	93	26NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	due to health problems
		1	93	26NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	due to health problems
	C4591001 1231 12314401	2	122	15JAN2021	REPEAT SCREENING 1	NO LONGER MEETS ELIGIBILITY CRITERIA	The volunteer receives methotrexate 15mg / day by mouth.
	C4591001 1231 12314661	2	161	22FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	personal motives
	C4591001 1231 12314863	1	28	24SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12314920	2	141	03FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	It's not interested in participating in the study if the research product is not brought to Argentina

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12315141	2	126	20JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	the participant reports having applied the Gam-COVID-Vac vaccine (trade name Sputnik V)
	C4591001 1231 12315324	2	136	31JAN2021	FOLLOW-UP	DEATH	DEATH/SEPTIC SHOCK
	C4591001 1231 12315565	2	123	22JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the subject will receive a vaccine against covid-19 outside the study protocol
	C4591001 1231 12315582	2	111	09JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	The participant received the Gam-COVID-Vac vaccine (trade name Sputnik V) on 07JAN2021
	C4591001 1231 12315604	2	166	03MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Impossibility of contacting the subject
	C4591001 1231 12315608	1	20	19SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12315612	2	125	21JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject decides to apply a different study vaccine
	C4591001 1231 12315619	2	45	05NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons.
		2	45	05NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons.
	C4591001 1231 12315634	2	35	23OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons.
		2	35	23OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12315672	1	22	21SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject in question decided to abandon the study for personal reasons.
		1	22	21SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject in question decided to abandon the study for personal reasons.
	C4591001 1232 12321128	2	163	25FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent from the study during unblinding
	C4591001 1232 12321196	2	147	24FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt was unblinded, Pt declined scheduling V101 and requested to be dropped from study.
	C4591001 1232 12321234	1	20	29SEP2020	VACCINATION	LOST TO FOLLOW-UP	Participant cannot be contacted, to be dropped from study
		1	20	29SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Participant cannot be contacted, to be dropped from study
	C4591001 1232 12321240	2	1	30SEP2020	VACCINATION	OTHER	Subject was initially lost to follow up but rejoined to study to receive vaccination 3
	C4591001 1232 12321242	1	1	11SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from the site
		1	1	11SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from the site
	C4591001 1232 12321281	1	1	29SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V2 and has not returned calls from the site
		1	1	29SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V2 and has not returned calls from the site

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1232 12321367	1	1	19OCT2020	VACCINATION	OTHER	Subject was initially lost to follow up but rejoined the study to receive vaccination 3
	C4591001 1232 12321432			28OCT2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject randomized in error
	C4591001 1241 12412568	1	9	12NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	patient meets exclusion criterion 5.
	C4591001 1246 12461132	2	101	08FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	No longer interested with onsite visits or completion of e-diary. Consented to telephonic contacts.
	C4591001 1247 12471066	1	17	15OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Patient tested positive for COVID 19 and was symptomatic prior to visit 2
	C4591001 1247 12471135	1	22	21OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/CEREBRAL INFARCTION
	C4591001 1248 12481026	1	23	20SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Withdrew due to time commitment. Mother is very sick and she is taking care of her
		1	23	20SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew prior to 2nd vaccination.
	C4591001 1248 12481041	2	107	04JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	received nonstudy COVID-19 vaccine
	C4591001 1248 12481163	2	93	05JAN2021	VACCINATION	PROTOCOL DEVIATION	crossover, revaccination V3 not performed/missed by the participant

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1248 12481182			16SEP2020	FOLLOW-UP	OTHER	Randomized but not dosed.
	C4591001 1248 12481214	1	26	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject stated he no longers want to to continue with study per phone call
		1	26	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wishes to continue
	C4591001 1251 12511092	2	118	20JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject does not want to continue in study and is unwilling to return for anymore visits.
	C4591001 1251 12511236	1	23	30OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		1	23	30OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1252 12521010	2	110	26DEC2020	FOLLOW-UP	DEATH	DEATH/COVID-19 PNEUMONIA
	C4591001 1254 12541013	2	119	14JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject made a decision to withdraw the study by getting the Moderna vaccine.
	C4591001 1258 12581076	2	57	18JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received the Moderna COVID Vaccine on 1-11-2021
	C4591001 1260 12601121	1	20	30SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	patient withdrew from study prior to vaccine # 2
		1	20	30SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal of consent

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1264 12641195	1	23	14OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DRY MOUTH
		1	23	14OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/ECZEMA
		1	23	14OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/PRURITUS
		1	23	14OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/RASH MACULO-PAPULAR
	C4591001 1265 12651015	2	147	09FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Withdrawn from the study due to receiving the vaccine outside of the study.
	C4591001 1265 12651050	2	140	08FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Withdrawn from the study due to receiving the COVID vaccine outside of the study.
	C4591001 1265 12651087	2	131	08FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	The patient received a non-study COVID-19 vaccine on 2/02/21.
	C4591001 1269 12691066	2	176	11MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received Moderna COVID-19 Vaccine
	C4591001 1269 12691124	2	1	29SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent
		2	1	29SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew consent
	C4591001 1270 12701057	1	61	02NOV2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/PULMONARY EMBOLISM
		1	132	12JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject plans to have COVID19 Vaccine outside of study on 12JAN2021/PULMONARY EMBOLISM

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 4444 44441152	1	22	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The volunteer expresses his desire to withdraw consent to participate in the study.
		1	22	12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The volunteer expresses his desire to withdraw consent to participate in the study
	C4591001 4444 44441389	2	144	06MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	The volunteer reports having applied the BBIBP-CorV vaccine (trade name Sinopharm COVID-19).
	C4591001 4444 44441495	1	24	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	for personal causes
		1	24	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	for personal causes
	C4591001 4444 44441792	1	9	01OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject, re-reads consent and decided it is not what she'd understood. Decides to revoke consent.
		1	9	01OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject rejects the terms of consent on a subsequent rereading.
	C4591001 4444 44442130	2	135	26FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	A vaccine not related to the study was applied.
	C4591001 4444 44442179	1	2	28SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject reports being sure that he received placebo and that he participated to receive the vaccine.
		1	2	28SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject reports being sure that he received placebo and that he participated to receive the vaccine.
	C4591001 4444 44442247	2	85	08JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	The participant applied the Gam-COVID-Vac vaccine (trade name Sputnik V) on 07 JAN 2021.

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16.2.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study – All Subjects ≥16 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment^b
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Note: † = Human immunodeficiency virus (HIV)-positive subject, ^ = Phase 1 subjects.

a. Relative day (Rel Day) = date of withdrawal - date of last vaccination + 1. For a withdrawal that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. MedDRA (v23.1) coding dictionary applied.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 27MAR2021 (00:55)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adds_1001_withdraw_all

**16.2.1.2 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects Enrolled in Multiple Sites – All Subjects ≥16 Years of Age**

Duplicate	Subject ID	Age Group (Years)	Subject	Dose No.	Rel Day^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment^b
1	10561101	16-55	C4591001 1056 10561101	2	44	03NOV2020	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT WAS FOUND AS A DUPLICATE FROM ANOTHER SITE IN CLOSE PROXIMITY.
	11331382	16-55	C4591001 1133 11331382	2	130	01FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent 11/DEC/2020
2	11101123	16-55	C4591001 1110 11101123	2	161	17FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Per sponsor request. Subject is in 2 site at the same time doing the same study.
	11331405	16-55	C4591001 1133 11331405						
3	11491117	>55	C4591001 1149 11491117	1	47	06OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent via phone call
				1	47	06OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent via phone conversation.
	12691090	>55	C4591001 1269 12691090	2	157	25FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
4	11351357	>55	C4591001 1135 11351357	2	149	04MAR2021	FOLLOW-UP	OTHER	dropped from study due to being enrolled at another site
	12691070	>55	C4591001 1269 12691070	2	167	03MAR2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject withdrawn due to being a duplicate subject
5	10891112	>55	C4591001 1089 10891112						

**16.2.1.2 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects Enrolled in Multiple Sites – All Subjects ≥16 Years of Age**

Duplicate	Subject ID	Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	11341006	>55	C4591001 1134 11341006						
6	10711213	16-55	C4591001 1071 10711213						
	11231105	16-55	C4591001 1123 11231105	2	178	26FEB2021	OPEN LABEL TREATMENT	PROTOCOL DEVIATION	Exclusion Number 12 & 16
				2	178	26FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Exclusion Number 12 & 16

a. Relative day (Rel Day) = date of withdrawal - date of last vaccination + 1. For a withdrawal that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. MedDRA (v23.1) coding dictionary applied.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 27MAR2021 (00:56)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adds_1001_wd_menrol_all