

### 16.2.5.2.1 Listing of Physical Examination With Abnormal Finding – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose No.	Rel Day <sup>a</sup>	Body System	Description
BNT162b1	18-55	10 µg	C4591001 1001 10011006	1	22	SKIN	PAPULES ON RIGHT BASE OF THUMB AND WRIST TO FOREARM, AND DERMATITIS ON THE RIGHT HAND.
			C4591001 1001 10011006	2	7	SKIN	BILATERAL ANTERIOR ARM / WRISTS FAIRLY ERYTHEMATOUS RASH, SCALY NOW, NON PRURITIC, IMPROVED FROM PREVIOUS VISIT STILL ONGOING SINCE 16MAY2020
			C4591001 1001 10011008	1	2	MUSCULOSKELETAL	MINIMAL TENDERNESS AT INJECTION SITE
			C4591001 1001 10011008	2	13	ABDOMEN	LEFT LOWER QUADRANT TENDERNESS
			C4591001 1001 10011009	1	2	MUSCULOSKELETAL	MILD TENDERNESS AT VACCINATION SITE
			C4591001 1001 10011009	2	14	EYES	L LATERAL ASPECT OF EYE- SLIGHT SWELLING AND PROMINENT VESSELS
			C4591001 1002 10021009	2	7	EXTREMITIES	MINIMAL ECCHYMOSIS AT LEFT UPPER EXTREMITY INJECTION SITE

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			C4591001 1002 10021013	2	7	EXTREMITIES	MILD TENDERNESS AT INJECTION SITE. LEFT ARM
		20 µg	C4591001 1001 10011067	1	22	THROAT	MILD POSTERIOR PHARYNGEAL ERYTHEMA WITH COBBLESTONING
			C4591001 1001 10011070		-8	EXTREMITIES	LEFT LEG SWOLLEN COMPARED TO RIGHT WITHOUT PITTING
			C4591001 1001 10011076	1	21	SKIN	LIGHT DESQUAMATION
			C4591001 1002 10021081	1	2	MUSCULOSKELETAL	MILD TENDERNESS TO PALPATION
			C4591001 1002 10021081	1	2	SKIN	NO ERYTHEMA OR SWELLING AT LEFT ARM INJECTION SITE
		30 µg	C4591001 1001 10011011	1	2	EXTREMITIES	LUE TENDERNESS, SWELLING, HYPERSENSITIVITY
			C4591001 1001 10011011	1	2	SKIN	LEFT UPPER ARM MILDLY HYPERSENSITIVE AND MILD SOFT, TENDER SWELLING: 3CM AREA AROUND INJECTION SITE; NO REDNESS; IT IS TENDER

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			C4591001 1001 10011011	2	8	MUSCULOSKELETAL	.5CM ECHYMOSIS AT THE INJECTION SITE IN LEFT DELTOID
			C4591001 1001 10011015	1	2	HEART	TACHYCARDIC
			C4591001 1001 10011015	1	2	MUSCULOSKELETAL	5CM INDURATION AT SITE OF INJECTION (LUE - DELTOID AREA)
			C4591001 1001 10011020	1	2	SKIN	SKIN: NO RASH NOTED. REDNESS MEASURING 18 UNITS ON THE MEASURING DEVICE, WITH ERYTHEMA AT INJECTION SITE IN LEFT DELTOID, MILD TENDERNESS TO PALPATION OF INJECTION SITE. (PLEASE SEE AE NOTE)
			C4591001 1002 10021014	1	2	EXTREMITIES	RIGHT ARM WITH TENDERNESS AT SITE OF INJECTION. NO ERYTHEMA OR SWELLING. FULL RANGE OF MOTION RIGHT SHOULDER
			C4591001 1002 10021014	2	7	EXTREMITIES	5MM (0.5CM) RESOLVING ECCHYMOSIS RIGHT DELTOID
			C4591001 1002 10021017	1	2	EXTREMITIES	LEFT SHOULDER WITH MILD DECREASED RANGE OF MOTION. NO ERYTHEMA/SWELLING

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			C4591001 1002 10021017	2	7	EXTREMITIES	1CM ECCHYMOSES ARM AT LEFT DELTOID. NO TENDERNESS OR REDNESS
			C4591001 1002 10021020	1	2	EXTREMITIES	TENDERNESS AT INJECTION SITE UPPER LEFT ARM. FULL RANGE OF MOTION LEFT SHOULDER. NO ERYTHEMA OR SWELLING
			C4591001 1002 10021020	1	21	LYMPH NODES	SHOTTY ANTERIOR CERVICAL LYMPHADENOPATHY
Placebo	18-55	Placebo	C4591001 1002 10021022	2	7	SKIN	BRUISING LEFT ARM AT INJECTION SITE
			C4591001 1002 10021083	1	8	EXTREMITIES	NO SWELLING
			C4591001 1002 10021083	1	8	SKIN	FAINT BRUISES, NON TENDER, NO NODULARY EDEMA
BNT162b1	65-85	10 µg	C4591001 1001 10011037	1	2	EXTREMITIES	MILD TENDERNESS TO PALPITATION OVER INJECTION SITE
			C4591001 1001 10011039		-6	SKIN	PAPULES ON BACK

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Vaccine Candidate	Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose No.	Rel Day <sup>a</sup>	Body System	Description
			C4591001 1001 10011039	1	1	SKIN	RASH
			C4591001 1001 10011040	2	8	MUSCULOSKELETAL	LEFT WRIST EXCORIATION FROM WEARING GLOVES AND WORKING
			C4591001 1001 10011044	1	2	HEART	IRREGULAR HR PART OF HIS MEDICAL HX
			C4591001 1001 10011045		-6	MUSCULOSKELETAL	ABLE TO LIFT ARMS AT SHOULDERS TO SLIGHTLY BEYOND 90 DEGREES UNABLE TO BRING ARMS BEHIND BACK, SLIGHT DEFORMITY OF RIGHT 2ND FINGER, MILDLY ENLARGED FINGER JOINTS
			C4591001 1001 10011045		-6	SKIN	RAISED, RED, NON-BLANCHING, NON-SCALING PATCH APPROXIMATELY 2 CM IN DIAMETER BEHIND LEFT EAR ON SCALP, NO OTHER RASHES
			C4591001 1001 10011045	1	1	MUSCULOSKELETAL	LIMITED ROM IN UPPER SHOULDER
			C4591001 1001 10011045	2	15	MUSCULOSKELETAL	1 CM ECCHYMOSIS TO LEFT DELTOID

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Vaccine Candidate	Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose No.	Rel Day <sup>a</sup>	Body System	Description
			C4591001 1002 10021043	1	8	EXTREMITIES	RIGHT THUMB BANDAGED/ STITCHES NO EDEMA
			C4591001 1002 10021045	1	2	EXTREMITIES	SMALL BRUISE AT INJECTION SITE LEFT ARM
		20 µg	C4591001 1001 10011050	1	2	EXTREMITIES	MILD TENDERNESS WITH
			C4591001 1001 10011055		-5	EXTREMITIES	R 4TH MCP WITH SOME LIMITATION OF ROM
			C4591001 1001 10011055	1	2	MUSCULOSKELETAL	TENDERNESS AT INJECTION SITE, GUARDED ROM LUE
			C4591001 1001 10011059	1	2	MUSCULOSKELETAL	TENDERNESS PRESENT, MILD TENDERNESS TO PALPATION, GUARDED ROM OF LUE
			C4591001 1001 10011059	1	22	EXTREMITIES	RIGHT LOWER LEG BELOW KNEE MILDLY SWOLLEN COMPARED TO LEFT WITHOUT PITTING EDEMA, MILD INDURATION OVER RIGHT UPPER LATERAL PORTION OF THE LOWER LEG. ALL RELATED TO FRACTURE AS NOTED IN AE

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Vaccine Candidate	Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose No.	Rel Day <sup>a</sup>	Body System	Description
			C4591001 1002 10021054	1	2	MUSCULOSKELETAL	LEFT UPPER EXTREMITY- TENDONS PALPATION
			C4591001 1002 10021060	1	2	MUSCULOSKELETAL	TENDER LEFT UPPER ARM TO PALPATION NO EDEMA NO ERYTHEMA
			C4591001 1002 10021060	1	8	SKIN	RESOLVED DERMATOMAL RASH
			C4591001 1002 10021068	2	9	EXTREMITIES	RIGHT INJECTION SITE TENDERNESS TO PALPATION
			C4591001 1002 10021071	1	2	EXTREMITIES	TENDERNESS TO PALPATION LEFT ARM AT VACCINATION SITE
		30 µg	C4591001 1001 10011046		-13	HEART	MILD BRADYCARDIA
			C4591001 1001 10011046		-13	MUSCULOSKELETAL	OCCASIONAL PAIN IN RIGHT KNEE
			C4591001 1001 10011046	2	15	EXTREMITIES	RIGHT ELBOW WITH LARGE ERYTHEMA, EXCORIATION COVERED WITH DRESSING, B/L PALMS WITH RESOLVING EXCORIATIONS, R KNEE BRUISE AND R THIGH EDEMA

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Vaccine Candidate	Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose No.	Rel Day <sup>a</sup>	Body System	Description
C4591001 1001 10011046				2	15	SKIN	RIGHT ELBOW WITH LARGE ERYTHEMA, EXCORIATION COVERED WITH DRESSING, B/L PALMS WITH RESOLVING EXCORIATIONS, R KNEE BRUISE AND R THIGH EDEMA
C4591001 1001 10011048				1	2	MUSCULOSKELETAL	MILD TENDERNESS
C4591001 1001 10011048				1	8	MUSCULOSKELETAL	MILD BRUISING OF DELTOID, MILD DISCOLORATION, 1 CM IN DIAMETER, CIRCULAR, NONTENDER
C4591001 1001 10011048				1	8	SKIN	FAINT OUTLINE OF BANDAID VISIBLE
C4591001 1001 10011058				1	1	SKIN	ECHYMOSIS IN IN MEDIAL LEFT ANTECUBITAL FOSSA
C4591001 1001 10011063				1	20	LYMPH NODES	LEFT AXILLARY SUBCENTIMETER LYMPH NODE
C4591001 1001 10011063				2	7	EXTREMITIES	LEFT ARM EXAM- SMALL SWELLING, NO ERYTHEMA, MILD TENDERNESS ON PALPATION, 4X2CM, NO BLISTERS, ABLE TO USE ARM WITHOUT ANY LIMITATION OF MOVEMENT



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Vaccine Candidate	Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose No.	Rel Day <sup>a</sup>	Body System	Description
			C4591001 1002 10021062	2	9	SKIN	FAINT ERYTHEMA NO SWELLING
			C4591001 1002 10021074	1	2	EXTREMITIES	MILD TENDERNESS AT INJECTION SITE, LEFT ARM
			C4591001 1002 10021075	1	2	EXTREMITIES	MILD INJECTION SITE TENDERNESS LEFT ARM
			C4591001 1002 10021077	1	2	MUSCULOSKELETAL	PAIN RAISING LEFT ARM
Placebo	65-85	Placebo	C4591001 1001 10011042	1	2	SKIN	LIGHT RED, NON-SCALY, NON-EXCORIATED RASH AROUND THE EDGE OF THE BANDAGE SITE
			C4591001 1001 10011053		-5	EXTREMITIES	RIGHT HAND 5TH DIP (DISTAL INTERPHALANGEAL JOINT) ABNORMAL RANGE OF MOTION
			C4591001 1001 10011053	1	2	SKIN	3MM VESICULAR LESION ON LEFT LOWER LIP WITH NO ASSOCIATED CELLULITIS
			C4591001 1001 10011053	1	8	SKIN	LEFT LOWER LIP WITH TWO LESIONS, CRUSTED CENTER VESICLE WITH SURROUNDING ERYTHEMATOUS BASE 2MM IN SIZE, NON TENDER

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Vaccine Candidate	Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose No.	Rel Day <sup>a</sup>	Body System	Description
			C4591001 1001 10011057		-5	EARS	TINNITUS
			C4591001 1001 10011057		-5	MUSCULOSKELETAL	MINIMAL CREPITUS AT FULL ROM L KNEE
			C4591001 1001 10011064		-2	HEART	BRADYCARDIA
BNT162b2	18-55	10 µg	C4591001 1003 10031019	1	2	EXTREMITIES	10MM INDIRATION AT INJECTION SITE NO REDNESS
			C4591001 1003 10031021	1	2	EXTREMITIES	LEFT ARM SLIGHTLY WARM NO REDNESS
			C4591001 1007 10071019	2	8	NOSE	BILATERAL NASAL MUCOSAL ERYTHEMA; BILATERAL CLEAR NASAL DRAINAGE
			C4591001 1007 10071019	2	8	THROAT	MILD ERYTHEMA; CLEAR DRAINAGE NOTED POSTERIOR PHARYNX
		20 µg	C4591001 1003 10031028		-11	EXTREMITIES	BRUISE ON LEFT LEG

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			C4591001 1003 10031028		-11	SKIN	RESOLVING SUNBURN
			C4591001 1003 10031028	2	8	SKIN	HAS A LARGE FLAT RED RASH ON RIGHT SUPRACLAVICULA ALSO ON UPPER BACK.
			C4591001 1007 10071026	2	8	SKIN	SCATTERED, MILDLY ERYTHEMATOUS PAPULAR RASH OVER THE RIGHT UPPER CHEST, APPROXIMATELY 3-4 CM IN DIAMETER. SIMILAR, PATCHY, MILDLY ERYTHEMATOUS PAPULAR RASH TO THE RIGHT SIDE OF HER FOREHEAD, TEMPLE
			C4591001 1007 10071027	1	2	EXTREMITIES	INJECTION SITE WITH MODERATE TENDERNESS
		30 µg	C4591001 1003 10031061	1	2	SKIN	SWEATY
			C4591001 1003 10031072		-5	EYES	CONGENITAL NYSTAGMUS
			C4591001 1003 10031072		-5	NEUROLOGICAL	CONGENITAL NYSTAGMUS

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			C4591001 1003 10031072	1	2	EXTREMITIES	FAINT AREA 5CM OF REDDNESS OVER VACCINE SITE
			C4591001 1007 10071050	2	4	LYMPH NODES	HAS 1X2 CM NON-TENDER, MOBILE NODE IN RIGHT AXILLAE
			C4591001 1007 10071064		-9	SKIN	MILD ROSACEA BILATERAL CHEEKS
Placebo	18-55	Placebo	C4591001 1007 10071020		-7	EXTREMITIES	RIGHT ANKLE WITH PAIN ON INVERSION STARTED 02JUN2020 AFTER NEW YOGA ROUTINE; MILD TINGLING IN RIGHT GREAT TOE; RESOLVING TODAY; EXAM NORMAL.
			C4591001 1007 10071025	1	22	SKIN	RIGHT LOWER VERMILION BORDER WITH A 4MM AND 6MM NONERYTHEMATOUS, ROUND LESION WITH CLEAR BORDER AND THIN CRUST
			C4591001 1007 10071065		-9	SKIN	2 BY 2 INCH PATCH OF POISON IVY LEFT UPPER INNER ARM.
			C4591001 1007 10071065	1	1	SKIN	3CM AREA ON LEFT MEDIAL THIGH WITH LIGHT GREENISH ECCHYMOSES AND SCATTERED ERYTHEMATOUS PAPULES WITHIN A 6CM AREA
BNT162b2	65-85	10 µg	C4591001 1003 10031076	2	8	LYMPH NODES	SINGLE LEFT AXILLARY NODE - NOT TENDER

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Vaccine Candidate	Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose No.	Rel Day <sup>a</sup>	Body System	Description
		20 µg	C4591001 1003 10031035	2	15	LYMPH NODES	LEFT AUXILIARY NODE 1 CM - NOT TENDER
			C4591001 1003 10031063	1	3	EXTREMITIES	BRUISES ON LEFT ARM FROM WORKING ON LAWN MOWER
			C4591001 1007 10071052	1	2	MUSCULOSKELETAL	RUQ MILD ABDOMINAL TENDERNESS
		30 µg	C4591001 1003 10031058	1	1	THROAT	LEFT LOWER GUM MILD SWELLING
			C4591001 1007 10071043	1	22	MUSCULOSKELETAL	PAIN IN LEFT HIP WITH STANDING AND TRUNCAL ROTATION
			C4591001 1007 10071043	1	22	EXTREMITIES	PAIN RADIATING DOWN LEFT LATERAL THIGH
Placebo	65-85	Placebo	C4591001 1003 10031036	1	22	LYMPH NODES	VERY SMALL LEFT AXILLARY NODE NOT TENDER
			C4591001 1003 10031083	1	7	MUSCULOSKELETAL	TENDER AT THE ANTERIOR OUTER RIGHT MID THORACIC RIBS

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<b>Vaccine Candidate</b>	<b>Age Group (Years)</b>	<b>Vaccine Group (as Randomized)</b>	<b>Subject</b>	<b>Dose No.</b>	<b>Rel Day<sup>a</sup></b>	<b>Body System</b>	<b>Description</b>
<p>a. Relative Day (Rel Day) = date of physical examination - date of last vaccination + 1. For a physical examination that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:33) Source Data: adpe Table Generation: 02SEP2020 (12:06)            (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adpe_l001_abn_p1</p>							

**16.2.5.2.1.1 Listing of Physical Examination With Abnormal Finding Before Dose 2 – Phase 1 – BNT162b1 (100 µg)**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose No.	Rel Day <sup>a</sup>	Body System	Description
BNT162b1	18-55	100 µg	C4591001 1001 10011028	1	38	SKIN	MACULAR RASH ON EXPOSED BILATERAL ARMS, UPPER CHEST
			C4591001 1001 10011030	1	2	MUSCULOSKELETAL	MILD TENDERNESS TO PALPATION
			C4591001 1001 10011032	1	2	EXTREMITIES	L ARM: 3X5CM TENDER SWELLING
			C4591001 1001 10011034	1	2	MUSCULOSKELETAL	TENDERNESS IS PRESENT WITH PALPITATION OF INJECTION SITE IN LEFT DELTOID. NO REDNESS OR SWELLING. THIS IS ABNORMAL AND NOT CLINICALLY SIGNIFICANT
			C4591001 1002 10021023	1	1	EXTREMITIES	LEFT UPPER ARM HEMANGIOMA
			C4591001 1002 10021023	1	2	EXTREMITIES	TENDERNESS TO DIRECT PALPATION AT INJECTION SITE
			C4591001 1002 10021024	1	2	EXTREMITIES	TENDERNESS TO LEFT ARM WITH PALPATION

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**16.2.5.2.1.1 Listing of Physical Examination With Abnormal Finding Before Dose 2 – Phase 1 – BNT162b1 (100 µg)**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose No.	Rel Day <sup>a</sup>	Body System	Description
			C4591001 1002 10021027	1	2	EXTREMITIES	TENDERNESS UPON PALPATION AT LEFT ARM
			C4591001 1002 10021034	1	2	EXTREMITIES	SORENESS/TENDERNESS AT INJECTION SITE LEFT ARM
			C4591001 1002 10021035	1	2	EXTREMITIES	TENDERNESS TO PALPATION AT LEFT ARM
			C4591001 1002 10021036	1	2	EXTREMITIES	TENDER TO PALPATION AT LEFT ARM
			C4591001 1002 10021036	1	28	HEAD	TENDERNESS OVER MAXILLARY SINUS
Placebo	18-55	Placebo	C4591001 1001 10011013		-13	SKIN	POSITIVE FOR RASHES

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

PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:33) Source Data: adpe Table Generation: 18SEP2020 (19:42)  
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001 IA P1 100/adpe 1001 abn 100 p1



## 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
16-55	C4591001 1012 10121103	2	22SEP2020	Product administration error	DOSE NOT CHANGED	N	N	22SEP2020	Y	N
	C4591001 1024 10241002	1	12AUG2020	Product storage error	DOSE NOT CHANGED	N	N	12AUG2020	N	N
		2	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1024 10241004	1	12AUG2020	Product storage error	DOSE NOT CHANGED	N	N	12AUG2020	N	N
		2	02SEP2020	Product storage error	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1024 10241006	1	12AUG2020	Product storage error	DOSE NOT CHANGED	N	N	12AUG2020	N	N
		2	02SEP2020	Product storage error	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1024 10241009	1	13AUG2020	Product storage error	DOSE NOT CHANGED	N	N	13AUG2020	N	N
	C4591001 1024 10241014	1	13AUG2020	Product storage error	DOSE NOT CHANGED	N	N	13AUG2020	N	N
		2	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1024 10241015	1	13AUG2020	Product storage error	DOSE NOT CHANGED	N	N	13AUG2020	N	N

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	C4591001 1024 10241021	1	14AUG2020	Product storage error	DOSE NOT CHANGED	N	N	14AUG2020	N	N
	C4591001 1024 10241023	1	14AUG2020	Product storage error	DOSE NOT CHANGED	N	N	14AUG2020	N	N
		2	02SEP2020	Product storage error	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1024 10241032	1	17AUG2020	Product storage error	DOSE NOT CHANGED	N	N	17AUG2020	N	N
	C4591001 1024 10241033	1	18AUG2020	Product storage error	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1024 10241039	1	18AUG2020	Product storage error	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1024 10241040	1	18AUG2020	Product storage error	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1024 10241042	1	19AUG2020	Product storage error	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1024 10241044	1	19AUG2020	Product storage error	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1024 10241046	1	19AUG2020	Product storage error	DOSE NOT CHANGED	N	N	19AUG2020	N	N

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	C4591001 1024 10241054	1	20AUG2020	Product storage error	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1024 10241055	1	20AUG2020	Product storage error	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1024 10241061	1	21AUG2020	Product storage error	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1024 10241066	1	24AUG2020	Product storage error	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1024 10241067	1	24AUG2020	Product storage error	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1024 10241071	1	24AUG2020	Product storage error	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1024 10241072	1	25AUG2020	Product storage error	DOSE NOT CHANGED	N	N	25AUG2020	N	N
	C4591001 1024 10241074	1	25AUG2020	Product storage error	DOSE NOT CHANGED	N	N	25AUG2020	N	N
	C4591001 1024 10241078	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1024 10241084	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N

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Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1024 10241085	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1024 10241091	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1024 10241094	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1024 10241100	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1024 10241102	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1024 10241104	1	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1024 10241108	1	02SEP2020	Product storage error	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1044 10441001	2	02SEP2020	Product temperature excursion issue	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1044 10441015	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1044 10441028		24AUG2020	Product storage error	DOSE NOT CHANGED	N	N	24AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1044 10441029	1	25AUG2020	Product storage error	DOSE NOT CHANGED	N	N	25AUG2020	N	N
	C4591001 1044 10441031	1	25AUG2020	Product storage error	DOSE NOT CHANGED	N	N	25AUG2020	N	N
	C4591001 1044 10441034	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1044 10441037	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1044 10441045	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1044 10441048		27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1044 10441050	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1044 10441052	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1044 10441054	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1044 10441060	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1044 10441063	1	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1044 10441068	1	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1044 10441071	1	02SEP2020	Product storage error	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1044 10441076	1	03SEP2020	Product storage error	DOSE NOT CHANGED	N	N	03SEP2020	N	N
	C4591001 1044 10441079	1	04SEP2020	Product storage error	DOSE NOT CHANGED	N	N	04SEP2020	N	N
	C4591001 1044 10441088	1	06SEP2020	Product storage error	DOSE NOT CHANGED	N	N	06SEP2020	N	N
	C4591001 1044 10441089	1	06SEP2020	Product storage error	DOSE NOT CHANGED	N	N	06SEP2020	N	N
	C4591001 1068 10681002	1	18AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1068 10681003	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681006	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1068 10681010	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681011	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681012	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681013	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681016	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681017	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681018	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681021	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681024	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681025	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1068 10681026	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681027	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681028	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681031	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681034	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681035	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681036	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681037	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681038	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681042	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N



### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1068 10681046	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681047	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681052	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681053	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681058	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681060	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681061	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681064	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681066	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681071	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1068 10681072	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681073	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681074	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681076	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681077	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681080	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681081	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681083	1	01SEP2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1079 10791130	1	17AUG2020	Wrong product administered	DRUG WITHDRAWN	N	N	17AUG2020	N	N
	C4591001 1088 10881077	2	11SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	11SEP2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1090 10901334	1	03SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	03SEP2020	N	N
	C4591001 1091 10911005	1	30JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	30JUL2020	N	N
	C4591001 1091 10911008	1	31JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1091 10911014	1	31JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1091 10911015	1	31JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1116 11161226	1	11SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	11SEP2020	N	N
	C4591001 1126 11261053	1	20AUG2020	Expired product administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1141 11411011	2	21AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1141 11411014	1	03AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	03AUG2020	N	N
	C4591001 1141 11411023	2	25AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	25AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1141 11411065	1	12AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	12AUG2020	N	N
	C4591001 1141 11411068	1	12AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	12AUG2020	N	N
	C4591001 1141 11411080	1	14AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	14AUG2020	N	N
	C4591001 1141 11411093	1	18AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1141 11411139	1	27AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1146 11461196	1	03SEP2020	Product administration error	DOSE NOT CHANGED	N	N	03SEP2020	N	N
	C4591001 1161 11611015	1	01AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	01AUG2020	N	N
	C4591001 1163 11631006	1	31JUL2020	Product administration error	DRUG WITHDRAWN	N	N	31JUL2020	N	N
	C4591001 1163 11631039	1	06AUG2020	Expired product administered	DOSE NOT CHANGED	N	N	06AUG2020	N	N
	C4591001 1163 11631096	1	12AUG2020	Expired product administered	DOSE NOT CHANGED	N	N	12AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1163 11631117	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631121	2	09SEP2020	Product storage error	DOSE NOT CHANGED	N	N	09SEP2020	N	N
	C4591001 1163 11631124	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631127	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631136	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631142	2	09SEP2020	Product storage error	DOSE NOT CHANGED	N	N	09SEP2020	N	N
	C4591001 1163 11631145	2	09SEP2020	Product storage error	DOSE NOT CHANGED	N	N	09SEP2020	N	N
	C4591001 1231 12313428	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313429	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313449	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1231 12313456	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313459	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313467	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313469	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313479	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313483	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313486	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313487	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313492	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313497	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1231 12313498	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313501	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313505	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313506	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313508	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313509	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313512	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313514	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313515	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313517	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1231 12313518	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313519	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313528	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313533	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313534	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313537	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313541	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313542	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313546	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313551	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N



### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1231 12313553	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313554	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313556	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313564	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313567	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1254 12541005	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1254 12541008	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1254 12541023	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1254 12541027	1	29AUG2020	Product storage error	DOSE NOT CHANGED	N	N	29AUG2020	N	N
	C4591001 1254 12541029	1	29AUG2020	Product storage error	DOSE NOT CHANGED	N	N	29AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1254 12541030	1	29AUG2020	Product storage error	DOSE NOT CHANGED	N	N	29AUG2020	N	N
	C4591001 1254 12541033	1	29AUG2020	Product storage error	DOSE NOT CHANGED	N	N	29AUG2020	N	N
	C4591001 1254 12541035	1	29AUG2020	Product storage error	DOSE NOT CHANGED	N	N	29AUG2020	N	N
	C4591001 1254 12541038	1	29AUG2020	Product storage error	DOSE NOT CHANGED	N	N	29AUG2020	N	N
	C4591001 1254 12541040	1	29AUG2020	Product storage error	DOSE NOT CHANGED	N	N	29AUG2020	N	N
	C4591001 1260 12601002	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1260 12601005	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1260 12601006	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1260 12601009	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1260 12601013	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1260 12601014	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1260 12601016	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1260 12601017	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1260 12601029	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1260 12601032	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1260 12601036	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N
>55	C4591001 1003 10031120	1	31JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1024 10241003	1	12AUG2020	Product storage error	DOSE NOT CHANGED	N	N	12AUG2020	N	N
		2	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1024 10241010	1	13AUG2020	Product storage error	DOSE NOT CHANGED	N	N	13AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1024 10241018	1	14AUG2020	Product storage error	DOSE NOT CHANGED	N	N	14AUG2020	N	N
	C4591001 1024 10241019	1	14AUG2020	Product storage error	DOSE NOT CHANGED	N	N	14AUG2020	N	N
	C4591001 1024 10241031	1	17AUG2020	Product storage error	DOSE NOT CHANGED	N	N	17AUG2020	N	N
	C4591001 1024 10241037	1	18AUG2020	Product storage error	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1024 10241041	1	18AUG2020	Product storage error	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1024 10241049	1	20AUG2020	Product storage error	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1024 10241057	1	21AUG2020	Product storage error	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1024 10241059	1	21AUG2020	Product storage error	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1024 10241065	1	24AUG2020	Product storage error	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1024 10241068	1	24AUG2020	Product storage error	DOSE NOT CHANGED	N	N	24AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1024 10241077	1	25AUG2020	Product storage error	DOSE NOT CHANGED	N	N	25AUG2020	N	N
	C4591001 1024 10241081	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1024 10241083	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1024 10241087	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1024 10241096	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1024 10241097	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1037 10371356	2	12NOV2020	Expired product administered	DOSE NOT CHANGED	N	N	12NOV2020	N	N
	C4591001 1044 10441002	2	02SEP2020	Product temperature excursion issue	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1044 10441004	2	02SEP2020	Product temperature excursion issue	DOSE NOT CHANGED	N	N	02SEP2020	N	N
	C4591001 1044 10441007	2	05SEP2020	Product storage error	DOSE NOT CHANGED	N	N	05SEP2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1044 10441010	2	06SEP2020	Product storage error	DOSE NOT CHANGED	N	N	06SEP2020	N	N
	C4591001 1044 10441016	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1044 10441018	1	20AUG2020	Product storage error	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1044 10441032	1	25AUG2020	Product storage error	DOSE NOT CHANGED	N	N	25AUG2020	N	N
	C4591001 1044 10441036	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1044 10441041	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1044 10441047	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1044 10441049	1	27AUG2020	Product storage error	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1044 10441055	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1044 10441062	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1044 10441067	1	01SEP2020	Product storage error	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1044 10441073	1	03SEP2020	Product storage error	DOSE NOT CHANGED	N	N	03SEP2020	N	N
	C4591001 1044 10441075	1	03SEP2020	Product storage error	DOSE NOT CHANGED	N	N	03SEP2020	N	N
	C4591001 1044 10441080	1	04SEP2020	Product storage error	DOSE NOT CHANGED	N	N	04SEP2020	N	N
	C4591001 1044 10441083	1	04SEP2020	Product storage error	DOSE NOT CHANGED	N	N	04SEP2020	N	N
	C4591001 1044 10441085	1	05SEP2020	Product storage error	DOSE NOT CHANGED	N	N	05SEP2020	N	N
	C4591001 1044 10441090	1	06SEP2020	Product storage error	DOSE NOT CHANGED	N	N	06SEP2020	N	N
	C4591001 1044 10441092	1	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1044 10441093	1	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1044 10441094	1	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1054 10541024	2	10OCT2020	Wrong product administered	DOSE NOT CHANGED	N	N	10OCT2020	N	N
	C4591001 1068 10681001	1	18AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001 1068 10681004	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681005	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681007	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681008	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681009	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001 1068 10681014	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681015	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1068 10681019	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N



### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1068 10681020	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681022	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681023	1	21AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	21AUG2020	N	N
	C4591001 1068 10681029	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681030	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681032	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681033	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001 1068 10681039	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681040	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681041	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1068 10681043	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681044	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681045	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1068 10681050	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681051	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681054	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681055	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681056	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681057	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1068 10681059	1	27AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1068 10681062	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681063	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681065	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681068	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681069	1	28AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1068 10681075	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681078	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681079	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681082	1	31AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1068 10681084	1	01SEP2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	01SEP2020	N	N

## 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1081 10811053	2	09SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	09SEP2020	N	N
	C4591001 1091 10911001	1	30JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	30JUL2020	N	N
	C4591001 1091 10911004	1	30JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	30JUL2020	N	N
	C4591001 1091 10911010	1	31JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1091 10911012	1	31JUL2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1121 11211071	1	03SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	03SEP2020	N	N
	C4591001 1129 11291091	2	01SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	01SEP2020	N	N
	C4591001 1141 11411066	1	12AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	12AUG2020	N	N
	C4591001 1163 11631003	1	31JUL2020	Expired product administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1163 11631005	1	31JUL2020	Product administration error	DRUG WITHDRAWN	N	N	31JUL2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1163 11631007	1	31JUL2020	Expired product administered	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1163 11631008	1	31JUL2020	Product administration error	DRUG WITHDRAWN	N	N	31JUL2020	N	N
	C4591001 1163 11631010	1	03AUG2020	Product administration error	DOSE NOT CHANGED	N	N	03AUG2020	N	N
	C4591001 1163 11631011	1	03AUG2020	Product administration error	DOSE NOT CHANGED	N	N	03AUG2020	N	N
	C4591001 1163 11631013	1	03AUG2020	Product administration error	DOSE NOT CHANGED	N	N	03AUG2020	N	N
	C4591001 1163 11631126	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631131	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631132	2	08SEP2020	Product storage error	DOSE NOT CHANGED	N	N	08SEP2020	N	N
	C4591001 1163 11631133	2	10SEP2020	Product storage error	DOSE NOT CHANGED	N	N	10SEP2020	N	N
	C4591001 1163 11631144	2	09SEP2020	Product storage error	DOSE NOT CHANGED	N	N	09SEP2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1163 11631149	2	09SEP2020	Product storage error	DOSE NOT CHANGED	N	N	09SEP2020	N	N
	C4591001 1177 11771089	2	09SEP2020	Wrong product administered	DOSE NOT CHANGED	N	N	09SEP2020	N	Y
	C4591001 1231 12311057	1	11AUG2020	Product dispensing error	DOSE NOT CHANGED	N	N	11AUG2020	N	N
	C4591001 1231 12313446	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313461	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313468	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313478	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313480	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313496	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313503	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1231 12313511	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313524	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313530	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313536	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313538	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313549	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313562	1	23AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1254 12541002	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1254 12541004	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1254 12541010	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N

### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1254 12541011	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1254 12541014	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1254 12541016	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1254 12541018	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1254 12541019	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1254 12541025	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1254 12541026	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001 1254 12541037	1	29AUG2020	Product storage error	DOSE NOT CHANGED	N	N	29AUG2020	N	N
	C4591001 1260 12601003	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001 1260 12601008	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N



### 16.2.5.4 Listing of Medication Errors – All Subjects

Age Group (Years)	Subject	Dose No. <sup>a</sup>	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Non-Drug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error Associated AE (Yes/No)
	C4591001 1260 12601025	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1260 12601026	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1260 12601027	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1260 12601033	1	31AUG2020	Product storage error	DOSE NOT CHANGED	N	N	31AUG2020	N	N
	C4591001 1265 12651026	1	31AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	31AUG2020	N	N

Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.

Note: † = HIV-positive subject.

a. Dose No. = the vaccination visit at which the medication error occurred.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 18NOV2020 (10:07)

(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2\_unblinded/C4591001\_IA\_P3\_2MPD2/adae\_1002\_me\_all\_p3