

### 16.2.7.1 Adverse Events Legend Page

Category	Abbreviation	Text
Action - Study Vaccine Dose	NA	Not applicable
	P	Investigational product withdrawn
Action - Subject	TC	Concomitant drug treatment given
	TCN	Concomitant non-drug treatment given
Cause of AE	CD	Concomitant drug treatment
	CND	Concomitant non-drug treatment
	O	Other
Outcome	N	Not recovered/not resolved
	R	Recovered/resolved
	RS	Recovered/resolved with sequelae
	RG	Recovering/resolving
Toxicity Grade	1	Mild
	2	Moderate
	3	Severe
	4	Life-threatening
System Organ Class	BLOOD	Blood and lymphatic system disorders
	CARD	Cardiac disorders
	CONG	Congenital, familial and genetic disorders
	EAR	Ear and labyrinth disorders
	ENDO	Endocrine disorders
	EYE	Eye disorders
	GASTR	Gastrointestinal disorders
	GENRL	General disorders and administration site conditions
	HEPAT	Hepatobiliary disorders
	IMMUN	Immune system disorders
	INFEC	Infections and infestations
	INJ&P	Injury poisoning and procedural complications
	INV	Investigations
METAB	Metabolism and nutrition disorders	

**16.2.7.1 Adverse Events Legend Page**

<b>Category</b>	<b>Abbreviation</b>	<b>Text</b>
	MUSC	Musculoskeletal and connective tissue disorders
	NEOPL	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
	NERV	Nervous system disorders
	PREG	Pregnancy, puerperium and perinatal conditions
	PSYCH	Psychiatric disorders
	RENAL	Renal and urinary disorders
	REPRO	Reproductive system and breast disorders
	RESP	Respiratory, thoracic and mediastinal disorders
	SKIN	Skin and subcutaneous tissue disorders
	SOCCL	Social circumstances
	SURG	Surgical and medical procedures
	VASC	Vascular disorders

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16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age													
Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
C4591001 1005 10051317/ BNT162b2 (30 µg)	12/F/ WHITE	GENRL	Chills/ CHILLS	1	21OCT2020	2/2	2	Yes		NA/TC	R (22OCT2020)	N/N	
C4591001 1005 10051328/ BNT162b2 (30 µg)	14/F/ WHITE	GASTR	Nausea/ NAUSEA	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N	
C4591001 1005 10051339/ Placebo	14/F/ WHITE	PSYCH	Anxiety/ anxiety	2	21APR2021	162/C	1	No	O	NA/TC	N	N/N	
		MUSC	Myalgia/ generalized myalgia#	3	19MAY2021	3/5	1	Yes		NA	R (23MAY2021)	N/N	
C4591001 1005 10051417/ Placebo	13/F/ WHITE	GENRL	Pyrexia/ fever#	4	13AUG2021	1/2	2	Yes		NA	R (14AUG2021)	N/N	
C4591001 1005 10051420/ BNT162b2 (30 µg)	12/F/ WHITE	PSYCH	Anxiety/ Anxiety	2	03MAY2021	120/C	1	No	O	NA/TC	N	N/N	
			Depression/ Depression	2	03MAY2021	120/C	1	No	O	NA/TC	N	N/N	
C4591001 1005 10051424/ Placebo	13/M/ WHITE	GASTR	Nausea/ NAUSEA	2	08JAN2021	1/4	1	Yes		NA/TC	R (11JAN2021)	N/N	

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BNT162b2 (30 µg)		GENRL	Fatigue/ FATIGUE	2	08JAN2021	1/4	2	Yes	NA	R (11JAN2021)	N/N	
			Injection site pain/ INJECTION SITE PAIN	2	08JAN2021	1/4	2	Yes	NA	R (11JAN2021)	N/N	
		MUSC	Myalgia/ GENERALIZED MYALGIA	2	08JAN2021	1/4	2	Yes	NA	R (11JAN2021)	N/N	
		NERV	Headache/ HEADACHE	2	08JAN2021	1/4	2	Yes	NA/TC	R (11JAN2021)	N/N	
C4591001 1005 10051427/ Placebo	14/F/ WHITE	GENRL	Chills/ chills#	4	07JUN2021	1/3	2	Yes	NA	R (09JUN2021)	N/N	
		MUSC	Myalgia/ generalized myalgia#	4	07JUN2021	1/3	2	Yes	NA	R (09JUN2021)	N/N	
C4591001 1005 10051437/ Placebo	15/F/ WHITE	GENRL	Fatigue/ Fatigue#	4	17JUN2021	1/10	2	Yes	NA	R (26JUN2021)	N/N	
		MUSC	Myalgia/ Generalized myalgia#	4	17JUN2021	1/10	2	Yes	NA	R (26JUN2021)	N/N	
C4591001 1005 10051449/ BNT162b2 (30 µg)	14/M/ WHITE	INFEC	Appendicitis/ Appendicitis#	2	28JUN2021	148/2	2	No	O	NA/TCN	R (29JUN2021)	Y/N

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C4591001 1005 10051450/ Placebo	14/M/ ASIAN	INJ&P	Hand fracture/ Broken left thumb#	3	10JUN2021	18/37	2	No	O	NA	R (16JUL2021)	N/N
C4591001 1006 10061183/ Placebo	14/M/ MULTIPLE	INJ&P	Hand fracture/ Broken thumb- left	2	12MAY2021	126/36	2	No	O	NA	R (16JUN2021)	N/N
		GENRL	Injection site pain/ Injection Site Tenderness#	3	20MAY2021	1/3	1	Yes		NA	R (22MAY2021)	N/N
C4591001 1006 10061196/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ Injection site tenderness#	3	19MAY2021	1/8	1	Yes		NA	R (26MAY2021)	N/N
C4591001 1006 10061203/ BNT162b2 (30 µg)	13/F/ WHITE	GASTR	Nausea/ Nausea	1	04DEC2020	2/1	1	Yes		NA	R (04DEC2020)	N/N
		GENRL	Fatigue/ Fatigue	1	04DEC2020	2/1	1	Yes		NA	R (04DEC2020)	N/N
			Injection site pain/ Injection site pain	1	04DEC2020	2/5	1	Yes		NA	R (08DEC2020)	N/N
		NERV	Headache/ Headache	1	04DEC2020	2/2	1	Yes		NA	R (05DEC2020)	N/N
		GENRL	Fatigue/ Fatigue	2	22DEC2020	1/3	1	Yes		NA	R (24DEC2020)	N/N
			Injection site pain/ Injection Site Pain	2	22DEC2020	1/3	2	Yes		NA	R (24DEC2020)	N/N

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C4591001 1006 10061209/ BNT162b2 (30 µg)	13/M/ WHITE	NERV	Headache/ Headache	2	22DEC2020	1/3	2	Yes		NA/TC	R (24DEC2020)	N/N
		NERV	Syncope/ Syncope Vasovagal response	2	12MAR2021	80/1	1	No	O	NA/TCN	R (12MAR2021)	N/N
C4591001 1006 10061223/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Injection Site Pain#	3	18MAY2021	2/4	1	Yes		NA/TC	R (21MAY2021)	N/N
C4591001 1006 10061226/ Placebo	15/F/ WHITE	PSYCH	Attention deficit hyperactivity disorder/ Attention Deficit Hyperactivity Disorder	2	24MAR2021	87/C	2	No	O	NA/TC	N	N/N
C4591001 1006 10061228/ Placebo	12/F/ WHITE	PSYCH	Attention deficit hyperactivity disorder/ Attention Deficit Hyperactivity Disorder	2	24MAR2021	86/C	2	No	O	NA/TC	N	N/N
C4591001 1006 10061245/ Placebo	15/M/ WHITE	SKIN	Urticaria/ Hives face	1	12DEC2020	3/20	1	Yes		NA/TC	R (31DEC2020)	N/N
			Urticaria/ Hives trunk	1	12DEC2020	3/4	1	Yes		NA/TC	R (15DEC2020)	N/N
C4591001 1006	14/M/ WHITE	INJ&P	Facial bones fracture/	3	02JUN2021	17/5	1	No	O	NA/TC	R (06JUN2021)	N/N

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10061253/ Placebo			Fractured Nasal Septum#									
C4591001 1006 10061258/ BNT162b2 (30 µg)	14/M/ NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	GASTR	Aphthous ulcer/ ORAL CANKERS#	2	27JUN2021	174/9	2	No	O	NA/TC	R (05JUL2021)	N/N
C4591001 1006 10061266/ Placebo	15/F/ MULTIPLE	GENRL	Chills/ CHILLS#	3	24FEB2021	1/3	2	Yes		NA/TC	R (26FEB2021)	N/N
C4591001 1006 10061272/ BNT162b2 (30 µg)	13/F/ BLACK OR AFRICAN AMERICAN	PSYCH	Anxiety/ Worsening of anxiety	1	23DEC2020	8/27	3	No	O	NA/TC/TCN	R (18JAN2021)	Y/N
			Depression/ Worsening of Depression	1	23DEC2020	8/27	3	No	O	NA/TC/TCN	R (18JAN2021)	Y/N
		INJ&P	Contusion/ Contusion left elbow	1	05FEB2021	52/29	1	No	O	NA	R (05MAR2021)	N/N
			Fall/ Fall	1	05FEB2021	52/1	1	No	O	NA	R (05FEB2021)	N/N
		GENRL	Injection site pain/ Injection site soreness#	2	17MAY2021	1/4	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1006 10061274/	14/F/ WHITE	NERV	Migraine/ MIGRAINE HEADACHES	2	APR2021	84/C	2	No	O	NA/TC	N	N/N

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BNT162b2 (30 µg)												
C4591001 1006 10061279/ Placebo	13/F/ WHITE	PSYCH	Anxiety/ Worsening of Anxiety	2	MAR2021	56/C	2	No	O	NA/TC	N	N/N
		INJ&P	Ligament sprain/ Left Sprained Ankle	2	26MAR2021	81/C	1	No	O	NA/TC/TCN	N	N/N
		NEOPL	Skin papilloma/ Left Foot Plantar Wart#	4	09JUN2021	3/9	2	No	O	NA/TCN	R (17JUN2021)	N/N
C4591001 1006 10061285/ Placebo	14/F/ WHITE	RENAL	Dysuria/ dysuria	2	31MAY2021	140/51	1	No	O	NA	R (20JUL2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	3	04JUN2021	2/2	2	Yes		NA	R (05JUN2021)	N/N
C4591001 1006 10061286/ BNT162b2 (30 µg)	14/M/ WHITE	GENRL	Fatigue/ FATIGUE	2	16JAN2021	6/4	2	Yes		NA	R (19JAN2021)	N/N
		INJ&P	Bone contusion/ CONTUSION RIGHT CALCANEUS	2	08MAR2021	57/C	2	No	O	NA/TCN	N	N/N
C4591001 1006 10061290/ BNT162b2 (30 µg)	15/F/ WHITE	INJ&P	Concussion/ Concussion	1	12JAN2021	22/32	2	No	O	NA/TC	R (12FEB2021)	N/N

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C4591001 1006 10061292/ Placebo	15/F/ WHITE	EAR	Cerumen impaction/ Earwax Impaction Left Ear	2	24JAN2021	13/5	2	No	O	NA/TCN	R (28JAN2021)	N/N
		INJ&P	Procedural pain/ Post Surgical pain Spinal hardware removal	2	30MAR2021	78/6	3	No	O	NA/TC	R (04APR2021)	N/N
C4591001 1007 10071409/ BNT162b2 (30 µg)	13/M/ ASIAN	GENRL	Fatigue/ fatigue#	2	28MAY2021	2/3	2	Yes		NA	R (30MAY2021)	N/N
			Injection site pain/ pain at injection site#	2	28MAY2021	2/4	1	Yes		NA	R (31MAY2021)	N/N
			Pyrexia/ fever#	2	28MAY2021	2/3	3	Yes		NA/TC	R (30MAY2021)	N/N
C4591001 1007 10071414/ Placebo	14/M/ WHITE	NERV	Headache/ headache#	2	28MAY2021	2/3	1	Yes		NA	R (30MAY2021)	N/N
		GENRL	Chills/ chills#	3	20MAY2021	2/3	2	Yes		NA	R (22MAY2021)	N/N
			Fatigue/ Fatigue#	3	20MAY2021	2/3	3	Yes		NA	R (22MAY2021)	N/N
C4591001 1007 10071476/ BNT162b2 (30 µg)	13/F/ WHITE	NERV	Syncope/ Vasovagal syncope without collapse*		30NOV2020	1/1	1	No	O	NA/TC/TCN	R (30NOV2020)	N/N

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C4591001 1007 10071480/ Placebo	14/M/ WHITE	NERV	Dizziness/ lightheadness after vaccination	2	21DEC2020	1/1	1	No	O	NA	R (21DEC2020)	N/Y
		GENRL	Injection site pain/ Injection site pain#	3	17MAY2021	1/8	1	Yes		NA	R (24MAY2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	4	08JUN2021	1/3	1	Yes		NA	R (10JUN2021)	N/N
		GENRL	Pyrexia/ fever#	4	09JUN2021	2/2	2	Yes		NA/TC	R (10JUN2021)	N/N
		NERV	Headache/ headache#	4	09JUN2021	2/2	2	Yes		NA/TC	R (10JUN2021)	N/N
		MUSC	Neck pain/ neck pain#	4	11JUN2021	4/C	2	No	O	NA	N	N/N
		INFEC	Herpes zoster/ shingles#	4	18JUN2021	11/13	2	No	O	NA	R (30JUN2021)	N/N
		MUSC	Pain in extremity/ Deltoid of left arm pain#	4	20JUN2021	13/4	2	No	O	NA	R (23JUN2021)	N/N
C4591001 1007 10071483/ Placebo	15/F/ WHITE	GENRL	Injection site pain/ Injection site pain#	3	30MAR2021	1/5	1	Yes		NA	R (03APR2021)	N/N
C4591001 1007 10071484/ Placebo	13/F/ WHITE	GENRL	Fatigue/ fatigue#	3	20MAY2021	2/34	1	Yes		NA	R (22JUN2021)	N/N
			Injection site pain/ injection site pain#	3	20MAY2021	2/1	1	Yes		NA	R (20MAY2021)	N/N

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		MUSC	Pyrexia/ subjective fever#	3	20MAY2021	2/3	1	Yes		NA	R (22MAY2021)	N/N
			Myalgia/ generalized muscle aches#	3	20MAY2021	2/3	1	Yes		NA	R (22MAY2021)	N/N
C4591001 1007 10071497/ BNT162b2 (30 µg)	12/M/ ASIAN	BLOOD	Lymphadenopathy/ swollen lymph node left axilla	2	25DEC2020	4/27	1	Yes		NA	R (20JAN2021)	N/N
C4591001 1007 10071499/ Placebo	14/M/ WHITE	MUSC	Arthralgia/ left wrist pain+	2	01MAY2021	131/3	1	No	O	NA/TC/TCN	R (03MAY2021)	N/N
C4591001 1007 10071500/ BNT162b2 (30 µg)	15/F/ WHITE	PSYCH	Sleep terror/ Night Terror	2	23DEC2020	2/1	1	No	O	NA	R (23DEC2020)	N/N
C4591001 1007 10071505/ Placebo	12/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	03JUN2021	2/2	1	Yes		NA	R (04JUN2021)	N/N
		MUSC	Pain in extremity/ Right Arm Pain#	3	03JUN2021	2/4	1	Yes		NA	R (06JUN2021)	N/N
		GENRL	Injection site pain/ injection site pain#	4	23JUN2021	1/3	1	Yes		NA	R (25JUN2021)	N/N
		GASTR	Nausea/ nausea#	4	24JUN2021	2/2	1	Yes		NA	R (25JUN2021)	N/N
		GENRL	Pyrexia/ fever 101#	4	24JUN2021	2/2	2	Yes		NA/TC	R (25JUN2021)	N/N

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		NERV	Dizziness/ lightheadedness#	4	24JUN2021	2/2	1	Yes		NA/TCN	R (25JUN2021)	N/N
			Headache/ headache#	4	24JUN2021	2/2	2	Yes		NA/TC	R (25JUN2021)	N/N
		NERV	Somnolence/ Excessive Sleepiness#	4	08JUL2021	16/15	3	No	O	NA	R (22JUL2021)	Y/N
C4591001 1007 10071509/ Placebo	15/F/ WHITE	MUSC	Pain in extremity/ Right Arm Pain#	3	21MAY2021	2/3	1	Yes		NA/TC	R (23MAY2021)	N/N
C4591001 1007 10071511/ Placebo	15/M/ WHITE	NERV	Headache/ Headache#	3	18MAY2021	1/2	1	Yes		NA	R (19MAY2021)	N/N
		MUSC	Pain in extremity/ Left arm pain#	3	19MAY2021	2/2	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1007 10071516/ Placebo	15/M/ WHITE	GENRL	Chills/ Chills#	3	19MAY2021	2/2	1	Yes		NA	R (20MAY2021)	N/N
			Pyrexia/ Fever#	3	19MAY2021	2/2	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1007 10071519/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	31MAR2021	1/2	2	Yes		NA	R (01APR2021)	N/N
C4591001 1007 10071524/ Placebo	15/M/ WHITE	INFEC	Candida infection/ thrush	2	01FEB2021	35/2	2	No	CD	NA	R (02FEB2021)	N/N

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C4591001 1007 10071531/ Placebo	14/F/ WHITE	NERV	Headache/ Headache#	3	26MAY2021	2/1	2	Yes		NA/TC	R (26MAY2021)	N/N
		GENRL	Injection site pain/ injection site pain#	3	22JUN2021	29/3	1	Yes		NA	R (24JUN2021)	N/N
		MUSC	Myalgia/ muscle aches to legs#	4	22JUN2021	1/3	1	Yes		NA	R (24JUN2021)	N/N
C4591001 1007 10071533/ Placebo	14/M/ WHITE	MUSC	Myalgia/ abdominal muscle pain	2	06JAN2021	8/2	1	No	O	NA/TC	R (07JAN2021)	N/N
C4591001 1007 10071547/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Injection site pain#	3	20MAY2021	1/3	1	Yes		NA	R (22MAY2021)	N/N
		GENRL	Injection site erythema/ Injection site redness#	3	21MAY2021	2/4	1	Yes		NA	R (24MAY2021)	N/N
C4591001 1007 10071559/ Placebo	14/F/ WHITE	GENRL	Fatigue/ fatigue#	3	28MAY2021	2/3	2	Yes		NA	R (30MAY2021)	N/N
		NERV	Dizziness/ dizziness#	3	28MAY2021	2/3	1	Yes		NA	R (30MAY2021)	N/N
		NERV	Headache/ headache#	3	28MAY2021	2/3	2	Yes		NA	R (30MAY2021)	N/N
		NERV	Headache/ headache#	3	05JUN2021	10/1	2	No	O	NA/TC	R (05JUN2021)	N/N

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C4591001 1007 10071562/ Placebo	12/F/ WHITE	GENRL	Chills/ chills#	4	17JUN2021	1/2	1	Yes		NA/TC	R (18JUN2021)	N/N
			Injection site pain/ injection site pain#	4	17JUN2021	1/3	1	Yes		NA	R (19JUN2021)	N/N
			Pyrexia/ fever 101.9#	4	17JUN2021	1/2	2	Yes		NA/TC	R (18JUN2021)	N/N
		MUSC	Myalgia/ generalized muscle pain#	4	17JUN2021	1/2	2	Yes		NA/TC	R (18JUN2021)	N/N
		NERV	Headache/ headache#	4	17JUN2021	1/2	1	Yes		NA	R (18JUN2021)	N/N
		GENRL	Fatigue/ fatigue#	3	18MAY2021	2/1	1	Yes		NA	R (18MAY2021)	N/N
		INV	Body temperature increased/ elevated body temp#	3	18MAY2021	2/1	2	Yes		NA/TC	R (18MAY2021)	N/N
		MUSC	Myalgia/ generalized muscle aches#	3	18MAY2021	2/1	1	Yes		NA	R (18MAY2021)	N/N
		INV	Body temperature increased/ elevated body temp 100.0#	4	07JUN2021	1/2	2	Yes		NA/TC	R (08JUN2021)	N/N
		GENRL	Fatigue/ fatigue#	4	08JUN2021	2/1	2	Yes		NA	R (08JUN2021)	N/N
MUSC	Myalgia/ generalized muscle aches#	4	08JUN2021	2/1	1	Yes		NA	R (08JUN2021)	N/N		

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1007 10071563/ Placebo	12/M/ WHITE	NERV	Dizziness/ lightheadness	1	14DEC2020	1/1	1	Yes		NA/TCN	R (14DEC2020)	N/Y
C4591001 1007 10071568/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ injection site soreness	1	15DEC2020	1/1	1	Yes		NA	R (15DEC2020)	N/Y
		SKIN	Rash maculo- papular/ maculopapular rash	2	05JAN2021	1/29	1	Yes		NA	R (02FEB2021)	N/Y
C4591001 1007 10071575/ BNT162b2 (30 µg)	15/M/ WHITE	INJ&P	Contusion/ Contusion of Left Arm	1	03JAN2021	19/11	2	No	O	NA/TC	R (13JAN2021)	N/N
C4591001 1007 10071581/ Placebo	15/M/ WHITE	INFEC	Appendicitis/ Appendicitis	2	10MAR2021	63/20	3	No	O	NA/TC	R (29MAR2021)	Y/N
		GENRL	Fatigue/ fatigue#	4	15JUN2021	2/2	2	Yes		NA	R (16JUN2021)	N/N
			Injection site pain/ injection site pain#	4	15JUN2021	2/2	1	Yes		NA	R (16JUN2021)	N/N
		MUSC	Myalgia/ generalized muscle aches#	4	15JUN2021	2/2	2	Yes		NA/TC	R (16JUN2021)	N/N
C4591001 1007 10071583/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ injection site pain#	4	09JUN2021	1/3	2	Yes		NA	R (11JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1007 10071584/ BNT162b2 (30 µg) C4591001 1007 10071585/ Placebo C4591001 1007 10071586/ Placebo C4591001 1007 10071593/ Placebo C4591001 1007 10071595/ Placebo C4591001 1007 10071596/ Placebo		NERV	Headache/ headache#	4	10JUN2021	2/1	1	Yes		NA	R (10JUN2021)	N/N
	15/M/ WHITE	GENRL	Injection site pain/ Soreness at injection site	2	07JAN2021	1/4	1	Yes		NA	R (10JAN2021)	N/Y
	12/M/ WHITE	SKIN	Urticaria/ hives; trunk, abdomen, back	2	16JAN2021	10/18	2	Yes		NA/TC	R (02FEB2021)	N/N
	13/M/ WHITE	GENRL	Injection site pain/ Injection site pain#	3	02JUN2021	2/3	1	Yes		NA	R (04JUN2021)	N/N
	15/M/ WHITE	INJ&P	Ligament sprain/ left Ankle sprain	1	30DEC2020	3/17	2	No	O	NA/TCN	R (15JAN2021)	N/N
	13/F/ WHITE	NERV	Presyncope/ Vaso-vagal response	2	30MAR2021	71/1	1	No	O	NA/TCN	R (30MAR2021)	N/N
	13/M/ WHITE	GENRL	Fatigue/ fatigue#	3	24MAY2021	1/5	2	Yes		NA	R (28MAY2021)	N/N
		NERV	Headache/ headache#	3	24MAY2021	1/5	2	Yes		NA	R (28MAY2021)	N/N
	GENRL	Pyrexia/ fever#	3	25MAY2021	2/4	1	Yes		NA	R (28MAY2021)	N/N	

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1007 10071600/ Placebo	12/F/ WHITE	MUSC	Myalgia/ muscle aches#	3	25MAY2021	2/4	2	Yes		NA	R (28MAY2021)	N/N
		PSYCH	Depression/ depression#	2	17MAY2021	119/C	2	No	O	NA/TC	RG	Y/N
C4591001 1007 10071613/ Placebo	13/M/ WHITE		Suicidal ideation/ Suicidal Ideation#	2	17MAY2021	119/5	3	No	O	NA/TC/TCN	R (21MAY2021)	Y/N
		GENRL	Injection site pain/ Pain at injection site	1	29DEC2020	1/1	1	Yes		NA	R (29DEC2020)	N/N
C4591001 1007 10071614/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ injection site soreness#	4	28JUN2021	1/4	1	Yes		NA	R (01JUL2021)	N/N
		GENRL	Chills/ chills#	4	29JUN2021	2/1	1	Yes		NA	R (29JUN2021)	N/N
C4591001 1007 10071615/ BNT162b2 (30 µg)	12/M/ WHITE		Fatigue/ fatigue#	4	29JUN2021	2/3	1	Yes		NA	R (01JUL2021)	N/N
			Pyrexia/ fever 101.9#	4	29JUN2021	2/3	2	Yes		NA	R (01JUL2021)	N/N
		NERV	Headache/ headache#	4	29JUN2021	2/1	1	Yes		NA	R (29JUN2021)	N/N
		BLOOD	Lymphadenopathy/ left axillary lymph node swelling	2	20JAN2021	2/4	1	Yes		NA	R (23JAN2021)	N/N

16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age													
Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
C4591001 1007 10071617/ Placebo	15/F/ WHITE	PSYCH	Anxiety/ worsening of Anxiety	2	15FEB2021	27/C	2	No	O	NA/TC	N	N/N	
			Obsessive- compulsive disorder/ worsening of Obsessive Compulsive Disorder	2	15FEB2021	27/C	2	No	O	NA/TC	N	N/N	
C4591001 1007 10071618/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ Pain at injection nsite	1	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/Y	
C4591001 1007 10071620/ BNT162b2 (30 µg)	12/F/ WHITE	GASTR	Abdominal pain/ Abdominal pain	2	21JAN2021	2/20	2	Yes		NA/TC	R (09FEB2021)	N/N	
		PSYCH	Conversion disorder/ generalized Functional neurologic disorder	2	21JAN2021	2/C	2	No	O	NA/TC	N	Y/N	
		INFEC	Vulval abscess/ Vulvar boil	2	24JAN2021	5/3	1	No	O	NA/TC	R (26JAN2021)	N/N	
		GASTR	Gastritis/ Gastritis	2	30JAN2021	11/	2	No	CD	NA/TC	R	N/N	
		PSYCH	Anxiety/ worsening anxiety	2	30JAN2021	11/C	2	No	O	NA/TC/TCN	N	N/N	

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1007 10071623/ Placebo	13/M/ WHITE	SKIN	Dermatitis contact/ contact dermatitis bilateral arms	2	12FEB2021	24/	1	No	O	NA/TC	R	N/N
		GASTR	Abdominal pain/ Functional Abdominal Pain	2	28FEB2021	40/C	3	No	O	NA/TC	N	Y/N
			Constipation/ Constipation	2	28FEB2021	40/14	3	No	O	NA/TC	R (13MAR2021)	Y/N
		GASTR	Constipation/ constipation	2	13MAR2021	53/C	2	No	O	NA/TC	RG	N/N
		GASTR	Toothache/ teeth pain	2	27JAN2021	7/2	2	No	CND	NA/TC	R (28JAN2021)	N/N
		MUSC	Tendonitis/ right wrist tendonitis	2	15FEB2021	26/176	2	No	O	NA/TC	RS (09AUG2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	01JUN2021	1/2	1	Yes		NA	R (02JUN2021)	N/N
C4591001 1007 10071624/ Placebo	13/M/ WHITE		Injection site pain/ Injection site pain#	3	01JUN2021	1/3	1	Yes		NA	R (03JUN2021)	N/N
		MUSC	Pain in extremity/ left Arm Pain#	3	20MAY2021	2/2	1	Yes		NA	R (21MAY2021)	N/N
C4591001 1007 10071625/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ Injection Site Arm Pain#	3	20MAY2021	2/2	1	Yes		NA	R (21MAY2021)	N/N
			Pyrexia/ fever#	3	20MAY2021	2/1	1	Yes		NA/TC	R (20MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1007 10071632/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ tenderness at injection site	1	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/Y
			Vessel puncture site pain/ pain at blood draw site	1	30DEC2020	1/2	1	No	O	NA	R (31DEC2020)	N/Y
		NERV	Headache/ headache	1	30DEC2020	1/1	1	Yes		NA	R (30DEC2020)	N/Y
		SKIN	Rash/ rash to chest and back	2	22JAN2021	2/5	2	Yes		NA	R (26JAN2021)	N/N
		GASTR	Nausea/ Nausea#	3	19MAY2021	2/1	1	Yes		NA	R (19MAY2021)	N/N
		GENRL	Pain/ Body ache#	3	19MAY2021	2/1	1	Yes		NA	R (19MAY2021)	N/N
		MUSC	Pain in extremity/ Arm pain#	3	19MAY2021	2/4	1	Yes		NA	R (22MAY2021)	N/N
		NERV	Headache/ Headache#	3	19MAY2021	2/1	1	Yes		NA	R (19MAY2021)	N/N
		GASTR	Nausea/ nausea#	4	09JUN2021	2/1	1	Yes		NA	R (09JUN2021)	N/N
		GENRL	Pain/ generalized body aches#	4	09JUN2021	2/1	2	Yes		NA/TC	R (09JUN2021)	N/N
C4591001 1007 10071634/ BNT162b2 (30 µg)	14/M/ WHITE	RESP	Rhinorrhoea/ Rhinorrhea	2	18FEB2021	25/C	1	No	O	NA	RG	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1007 10071640/ Placebo	14/F/ WHITE	NERV	Presyncope/ vasovagal response	2	22FEB2021	29/1	1	No	O	NA	R (22FEB2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	3	03JUN2021	1/2	1	Yes		NA	R (04JUN2021)	N/N
		GENRL	Chills/ Chills#	4	22JUN2021	1/2	1	Yes		NA	R (23JUN2021)	N/N
			Pyrexia/ fever#	4	22JUN2021	1/2	1	Yes		NA/TC/TCN	R (23JUN2021)	N/N
C4591001 1007 10071642/ BNT162b2 (30 µg)	15/M/ WHITE	NERV	Headache/ headache#	4	22JUN2021	1/2	2	Yes		NA/TC	R (23JUN2021)	N/N
		GENRL	Fatigue/ fatigue#	2	28MAY2021	2/2	2	Yes		NA	R (29MAY2021)	N/N
			Pain/ body aches#	2	28MAY2021	2/2	2	Yes		NA	R (29MAY2021)	N/N
			Pyrexia/ fever 103.5#	2	28MAY2021	2/2	3	Yes		NA/TC	R (29MAY2021)	N/N
C4591001 1007 10071648/ Placebo	15/M/ ASIAN	NERV	Dizziness/ dizziness#	2	28MAY2021	2/2	1	Yes		NA	R (29MAY2021)	N/N
			Headache/ headache#	2	28MAY2021	2/2	1	Yes		NA	R (29MAY2021)	N/N
		GENRL	Injection site pain/ Injection site pain	2	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/Y
C4591001 1007	13/M/ WHITE	NERV	Headache/ Headache#	4	15JUN2021	1/2	2	Yes		NA/TC	R (16JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
10071650/ Placebo		GENRL	Chest discomfort/ chest tightness#	4	16JUN2021	2/1	1	No	O	NA/TC	R (16JUN2021)	N/N
			Chills/ chills#	4	16JUN2021	2/1	1	Yes		NA/TC	R (16JUN2021)	N/N
			Fatigue/ fatigue#	4	16JUN2021	2/1	1	Yes		NA/TC	R (16JUN2021)	N/N
			Injection site pain/ injection site pain#	4	16JUN2021	2/1	1	Yes		NA/TC	R (16JUN2021)	N/N
		INV	Body temperature increased/ elevated body temperature unknown temp#	4	16JUN2021	2/1	1	Yes		NA/TC	R (16JUN2021)	N/N
		MUSC	Myalgia/ generalized muscle aches#	4	16JUN2021	2/1	2	Yes		NA/TC	R (16JUN2021)	N/N
C4591001 1007 10071651/ BNT162b2 (30 µg)	12/M/ WHITE	BLOOD	Lymphadenopathy/ Left deep cervical chain lymph node swelling	1	12JAN2021	8/29	1	Yes		NA	R (09FEB2021)	N/N
		BLOOD	Lymphadenopathy/ left Cervical lymphadenopathy	2	23FEB2021	29/15	1	No	O	NA	R (09MAR2021)	N/N
C4591001 1007 10071652/ Placebo	12/F/ WHITE	GENRL	Injection site erythema/ Erythema at injection site#	4	21JUN2021	1/2	1	Yes		NA	R (22JUN2021)	N/Y

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1007 10071658/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ injection site pain#	4	07JUN2021	1/4	1	Yes		NA/TC	R (10JUN2021)	N/N
			Malaise/ malaise#	4	07JUN2021	1/4	3	Yes		NA/TC	R (10JUN2021)	N/N
			Pyrexia/ fever#	4	07JUN2021	1/3	1	Yes		NA/TC	R (09JUN2021)	N/N
		MUSC	Myalgia/ generalized myalgia#	4	07JUN2021	1/4	3	Yes		NA/TC	R (10JUN2021)	N/N
		MUSC	Musculoskeletal chest pain/ anterior chest wall pain#	4	08JUN2021	2/1	3	Yes		NA/TC	R (08JUN2021)	N/N
		NERV	Headache/ headache#	4	08JUN2021	2/3	2	Yes		NA/TC	R (10JUN2021)	N/N
C4591001 1007 10071660/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ injection site pain#	3	02JUN2021	1/3	2	Yes		NA	R (04JUN2021)	N/N
		GENRL	Chills/ chills#	3	03JUN2021	2/2	1	Yes		NA	R (04JUN2021)	N/N
			Pyrexia/ fever 101.4#	3	03JUN2021	2/2	2	Yes		NA	R (04JUN2021)	N/N
		GENRL	Injection site pain/ injection site pain#	4	24JUN2021	1/2	1	Yes		NA	R (25JUN2021)	N/Y
		GENRL	Fatigue/ fatigue#	4	25JUN2021	2/2	2	Yes		NA	R (26JUN2021)	N/N
C4591001 1008	15/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	05APR2021	1/2	1	Yes		NA	R (06APR2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
10081761/ Placebo C4591001 1008 10081781/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ injection site pain#	4	10JUN2021	2/3	1	Yes		NA	R (12JUN2021)	N/N
			Injection site reaction/ injection site fatigue#	4	10JUN2021	2/3	1	Yes		NA	R (12JUN2021)	N/N
C4591001 1008 10081788/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ injection site pain#	3	13MAY2021	1/2	1	Yes		NA	R (14MAY2021)	N/N
C4591001 1008 10081801/ Placebo	15/F/ WHITE	GENRL	Fatigue/ Fatigue#	4	08JUN2021	2/2	1	Yes		NA	R (09JUN2021)	N/N
C4591001 1008 10081808/ Placebo	13/M/ ASIAN	GENRL	Fatigue/ Fatigue#	3	18MAY2021	2/2	1	Yes		NA	R (19MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	08JUN2021	2/2	1	Yes		NA	R (09JUN2021)	N/N
C4591001 1008 10081812/ Placebo	14/M/ WHITE	NERV	Headache/ headache#	3	14MAY2021	2/2	2	Yes		NA/TC	R (15MAY2021)	N/N
C4591001 1008	12/M/ WHITE	GENRL	Fatigue/ Fatigue#	3	20MAY2021	2/2	2	Yes		NA	R (21MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Cause of Vax Rel <sup>c</sup> AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
10081837/ Placebo			Pain/ body aches#	3	20MAY2021	2/2	2	Yes	NA/TC	R (21MAY2021)	N/N
		NERV	Headache/ headache#	3	20MAY2021	2/2	2	Yes	NA/TC	R (21MAY2021)	N/N
C4591001 1008 10081844/ Placebo	12/M/ WHITE	GASTR	Nausea/ nausea#	3	19MAY2021	1/2	1	Yes	NA	R (20MAY2021)	N/N
		GENRL	Pain/ body aches#	3	20MAY2021	2/1	1	Yes	NA	R (20MAY2021)	N/N
		NERV	Headache/ headache#	3	20MAY2021	2/1	1	Yes	NA/TC	R (20MAY2021)	N/N
C4591001 1008 10081863/ Placebo	13/F/ ASIAN	GENRL	Pain/ Body Aches#	4	08JUN2021	2/2	1	Yes	NA	R (09JUN2021)	N/N
		NERV	Headache/ Headache#	4	08JUN2021	2/2	1	Yes	NA	R (09JUN2021)	N/N
C4591001 1008 10081877/ Placebo	14/M/ WHITE	GENRL	Fatigue/ fatigue#	3	17MAY2021	1/3	2	Yes	NA	R (19MAY2021)	N/N
		GENRL	Pain/ body aches#	3	18MAY2021	2/2	2	Yes	NA	R (19MAY2021)	N/N
C4591001 1008 10081887/ Placebo	12/F/ WHITE	GENRL	Chills/ chills#	3	14MAY2021	2/4	1	Yes	NA	R (17MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		NERV	Headache/ headache#	3	14MAY2021	2/4	2	Yes		NA	R (17MAY2021)	N/N
		SKIN	Hyperhidrosis/ sweating#	3	14MAY2021	2/4	1	Yes		NA	R (17MAY2021)	N/N
C4591001 1008 10081892/ Placebo	14/M/ AMERICAN INDIAN OR ALASKA NATIVE	GENRL	Injection site pain/ injection site pain#	3	25MAY2021	1/5	1	Yes		NA	R (29MAY2021)	N/N
C4591001 1008 10081913/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ injection site pain#	2	16MAY2021	109/4	1	Yes		NA	R (19MAY2021)	N/N
C4591001 1008 10081928/ BNT162b2 (30 µg)	13/F/ WHITE	SKIN	Urticaria/ urticaria multiple sites	1	10JAN2021	3/13	1	Yes		NA/TC	R (22JAN2021)	N/N
C4591001 1008 10081931/ Placebo	12/M/ ASIAN	INFEC	Cellulitis/ Cellulitis left leg	2	15MAR2021	43/5	1	No	O	NA/TC	R (19MAR2021)	N/N
C4591001 1008 10081933/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ injection site pain#	4	08JUN2021	2/2	1	Yes		NA	R (09JUN2021)	N/N
C4591001 1009 10091220/ Placebo	15/M/ WHITE	INJ&P	Procedural pain/ POST SURGICAL PAIN, ORAL	2	20NOV2020	14/11	2	No	O	NA/TC	R (30NOV2020)	N/N

16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age													
Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
C4591001 1009 10091221/ BNT162b2 (30 µg)	14/F/ WHITE	MUSC	Arthralgia/ worsening right ankle pain	1	19OCT2020	1/1	3	No	O	NA/TCN	R (19OCT2020)	N/N	
C4591001 1009 10091229/ Placebo	12/F/ WHITE	GENRL	Pain/ Body Aches following vaccination#	3	22MAY2021	2/2	2	Yes		NA/TC	R (23MAY2021)	N/N	
C4591001 1009 10091231/ BNT162b2 (30 µg)	15/M/ ASIAN	BLOOD	Lymphadenopathy/ left swollen axillary lymph node	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N	
C4591001 1009 10091267/ Placebo	13/M/ WHITE	RESP	Rhinorrhoea/ RUNNY NOSE	2	27DEC2020	6/6	1	No	O	NA/TC	R (01JAN2021)	N/N	
C4591001 1009 10091294/ Placebo	15/F/ WHITE	MUSC	Arthralgia/ bilateral shoulder pain	1	22DEC2020	16/3	1	No	O	NA	R (24DEC2020)	N/N	
C4591001 1009 10091301/ Placebo	15/F/ WHITE	GENRL	Pain/ body aches#	3	06APR2021	1/2	1	Yes		NA	R (07APR2021)	N/N	
C4591001 1009 10091301/ Placebo	15/F/ WHITE	INJ&P	Arthropod bite/ spider bite#	4	22JUL2021	32/15	2	No	O	NA/TC	R (05AUG2021)	N/N	
C4591001 1009 10091305/ Placebo	15/F/ WHITE	BLOOD	Lymphadenitis/ Right Axillary Adenitis#	3	24MAR2021	6/24	2	Yes		NA/TC	R (16APR2021)	N/N	

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1009 10091319/ BNT162b2 (30 µg)	15/M/ WHITE	NERV	Headache/ headache	2	22JAN2021	25/1	2	No	O	NA	R (22JAN2021)	N/N
C4591001 1009 10091323/ Placebo	15/F/ WHITE	GASTR	Nausea/ nausea	2	08JAN2021	10/1	1	No	O	NA	R (08JAN2021)	N/N
		GENRL	Fatigue/ fatigue	2	08JAN2021	10/1	1	No	O	NA	R (08JAN2021)	N/N
C4591001 1009 10091326/ Placebo	12/F/ WHITE	GENRL	Injection site pain/ Sore (pain) left deltoid- at injection site#	4	26JUN2021	2/1	1	Yes		NA	R (26JUN2021)	N/N
		NERV	Headache/ headache#	4	26JUN2021	2/1	1	Yes		NA	R (26JUN2021)	N/N
C4591001 1009 10091334/ Placebo	13/F/ WHITE	RESP	Rhinorrhoea/ runny nose	2	11JAN2021	12/1	1	No	O	NA	R (11JAN2021)	N/N
C4591001 1009 10091338/ Placebo	15/F/ WHITE	SURG	Wisdom teeth removal/ Wisdom Teeth Removal	1	08JUN2021	177/1	2	No	O	NA/TC	R (08JUN2021)	N/N
		GASTR	Mouth ulceration/ Mouth Ulcer	1	16JUN2021	185/6	2	No	O	NA/TC	R (21JUN2021)	N/N
C4591001 1009 10091341/ Placebo	13/M/ WHITE	GENRL	Pain/ body aches#	3	03JUL2021	2/1	1	Yes		NA	R (03JUL2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1009 10091342/ BNT162b2 (30 µg)	15/M/ WHITE	BLOOD	Lymphadenopathy/ swollen cervical lymph nodes bilateral	2	31JAN2021	28/3	1	No	O	NA	R (02FEB2021)	N/N
C4591001 1009 10091357/ Placebo	15/M/ WHITE	CONG	Spine malformation/ congenital vertebral pedicle hypoplasia	2	12FEB2021	39/C	1	No	O	NA	N	N/N
		GENRL	Pain/ body aches#	4	06APR2021	2/2	1	Yes		NA	R (07APR2021)	N/N
		NERV	Headache/ headache#	4	06APR2021	2/2	1	Yes		NA	R (07APR2021)	N/N
C4591001 1009 10091361/ Placebo	13/F/ WHITE	INJ&P	Ligament sprain/ sprained right thumb	1	02JAN2021	17/30	2	No	O	NA	R (31JAN2021)	N/N
C4591001 1009 10091363/ Placebo	14/M/ WHITE	NERV	Presyncope/ Vasovagal Reaction	1	09FEB2021	55/1	1	No	O	NA	R (09FEB2021)	N/N
C4591001 1009 10091365/ Placebo	12/M/ WHITE	INJ&P	Upper limb fracture/ right arm fracture	2	19MAR2021	60/C	2	No	O	NA/TC	RG	N/N
C4591001 1009 10091366/ Placebo	14/F/ WHITE	GENRL	Injection site pain/ Mild Injection Site Pain	2	26FEB2021	1/2	1	Yes		NA	R (27FEB2021)	N/N
C4591001 1009	13/F/ WHITE	NERV	Headache/ headache	1	06JAN2021	20/1	3	No	O	NA/TC	R (06JAN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Cause of Vax Rel <sup>c</sup>	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
10091370/ BNT162b2 (30 µg)												
C4591001 1009 10091379/ Placebo	13/F/ WHITE	INJ&P	Fall/ GROUND LEVEL FALL	2	26FEB2021	44/1	2	No	O	NA	R (26FEB2021)	N/N
		INJ&P	Contusion/ BRUISED KNEE, LEFT	2	22MAR2021	68/19	2	No	O	NA/TC	R (09APR2021)	N/N
		SKIN	Ingrowing nail/ bilateral great toe ingrown toenail#	3	03JUN2021	16/C	1	No	O	NA/TC	N	N/N
C4591001 1009 10091380/ Placebo	14/M/ WHITE	INJ&P	Clavicle fracture/ Right Clavicle Fracture	1	18JAN2021	21/36	2	No	O	NA/TC	R (22FEB2021)	N/N
		INJ&P	Procedural pain/ pain after wisdom teeth removal	2	11FEB2021	24/5	1	No	O	NA/TC	R (15FEB2021)	N/N
C4591001 1009 10091382/ Placebo	14/F/ WHITE	MUSC	Arthralgia/ RIGHT KNEE PAIN	1	10JAN2021	7/16	2	No	O	NA	R (25JAN2021)	N/N
		GASTR	Nausea/ nausea#	3	15MAY2021	2/3	1	Yes		NA	R (17MAY2021)	N/N
		MUSC	Myalgia/ generalized muscle pain#	3	15MAY2021	2/6	1	Yes		NA	R (20MAY2021)	N/N
		NERV	Dizziness/ dizziness#	3	15MAY2021	2/2	1	Yes		NA	R (16MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1009 10091399/ Placebo	12/F/ WHITE	RESP	Rhinorrhoea/ rhinorrhea#	3	15MAY2021	2/3	1	Yes		NA	R (17MAY2021)	N/N
		GENRL	Chills/ chills#	4	03JUN2021	2/1	1	Yes		NA	R (03JUN2021)	N/N
C4591001 1009 10091400/ Placebo	12/M/ WHITE	INJ&P	Foot fracture/ Left Fifth Metatarsal Fracture	2	23FEB2021	26/82	2	No	O	NA/TC	R (15MAY2021)	N/N
C4591001 1009 10091401/ Placebo	12/M/ WHITE	SKIN	Eczema/ Eczema generalized	2	02APR2021	50/3	2	No	O	NA	R (04APR2021)	N/N
		SKIN	Urticaria/ Urticaria generalized	2	07APR2021	55/8	3	No	O	NA/TC	R (14APR2021)	N/N
C4591001 1009 10091401/ Placebo	12/M/ WHITE	EAR	Motion sickness/ motion sickness#	3	08AUG2021	7/1	1	No	O	NA	R (08AUG2021)	N/N
C4591001 1009 10091403/ Placebo	15/F/ WHITE	RESP	Rhinorrhoea/ runny nose	1	10JAN2021	3/4	1	Yes		NA	R (13JAN2021)	N/N
C4591001 1009 10091405/ Placebo	15/F/ WHITE	BLOOD	Lymphadenopathy/ left axillary adenopathy#	4	20AUG2021	2/C	1	Yes		NA	N	N/N
		GENRL	Fatigue/ fatigue#	4	20AUG2021	2/2	2	Yes		NA	R (21AUG2021)	N/N
			Pyrexia/ fever#	4	20AUG2021	2/1	1	Yes		NA/TC	R (20AUG2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1009 10091406/ Placebo	15/M/ WHITE	NERV	Headache/ headache#	4	20AUG2021	2/2	1	Yes		NA	R (21AUG2021)	N/N
		MUSC	Joint swelling/ Swilling in bilateral knees	1	25JAN2021	18/36	1	No	O	NA/TC	R (01MAR2021)	N/N
		GENRL	Fatigue/ fatigue#	4	20AUG2021	2/2	2	Yes		NA	R (21AUG2021)	N/N
			Pyrexia/ fever#	4	20AUG2021	2/2	1	Yes		NA	R (21AUG2021)	N/N
C4591001 1009 10091409/ BNT162b2 (30 µg)	14/F/ WHITE	NERV	Headache/ headache#	4	20AUG2021	2/2	1	Yes		NA	R (21AUG2021)	N/N
		INJ&P	Procedural pain/ Post Surgical Pain	2	22JUL2021	171/C	2	No	O	NA/TC	N	N/N
C4591001 1009 10091410/ BNT162b2 (30 µg)	12/F/ WHITE	GENRL	Fatigue/ FATIGUE	2	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
C4591001 1009 10091413/ BNT162b2 (30 µg)	13/F/ WHITE	MUSC	Musculoskeletal chest pain/ bilateral rib pain	2	05FEB2021	3/1	2	Yes		NA/TC	R (05FEB2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		INJ&P	Femur fracture/ Right Intertrochanteric Femur Fracture	2	13MAR2021	39/4	3	No	O	NA/TC/TCN	R (16MAR2021)	Y/N
		INJ&P	Procedural pain/ Post Surgical Right Leg Pain	2	16MAR2021	42/15	2	No	O	NA/TC	R (30MAR2021)	N/N
C4591001 1013 10131824/ BNT162b2 (30 µg)	14/F/ BLACK OR AFRICAN AMERICAN	GENRL	Peripheral swelling/ SWELLING LEFT ARM	1	05DEC2020	5/2	1	Yes		NA	R (06DEC2020)	N/N
C4591001 1013 10131839/ Placebo	14/F/ WHITE	INJ&P	Concussion/ SPORTS RELATED CONCUSSION	2	01MAR2021	69/C	2	No	O	NA	RG	N/N
C4591001 1016 10161316/ Placebo	15/M/ WHITE	GENRL	Chills/ chills#	3	26FEB2021	2/1	2	Yes		NA	R (26FEB2021)	N/N
		MUSC	Myalgia/ muscle pain#	3	26FEB2021	2/1	2	Yes		NA/TC	R (26FEB2021)	N/N
C4591001 1016 10161327/ Placebo	12/M/ WHITE	NERV	Syncope/ syncope	2	09APR2021	151/1	2	No	O	NA	R (09APR2021)	N/N
		NERV	Epilepsy/ epilepsy#	4	29JUN2021	8/C	2	No	O	NA	N	Y/N
C4591001 1016	14/M/ WHITE	INJ&P	Wound/ left foot puncture wound#	4	04JUL2021	26/21	1	No	O	NA	R (24JUL2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
10161329/ Placebo		INFEC	Cellulitis/ cellulitis of left foot#	4	06JUL2021	28/11	1	No	O	NA/TC	R (16JUL2021)	N/N
C4591001 1016 10161344/ Placebo	15/F/ WHITE	BLOOD	Lymphadenopathy/ enlarged lymph nodes, right anterior cervical nodes	2	25NOV2020	15/43	1	No	O	NA	R (06JAN2021)	N/N
		INFEC	Infectious mononucleosis/ infectious mononucleosis	2	25NOV2020	15/43	1	No	O	NA	R (06JAN2021)	N/N
C4591001 1016 10161353/ Placebo	13/F/ WHITE	GENRL	Chills/ chills#	3	25MAY2021	2/2	2	Yes		NA	R (26MAY2021)	N/N
			Fatigue/ fatigue#	3	25MAY2021	2/2	2	Yes		NA	R (26MAY2021)	N/N
			Injection site pain/ left deltoid injection site soreness#	3	25MAY2021	2/2	1	Yes		NA	R (26MAY2021)	N/N
		GENRL	Chills/ chills#	4	14JUN2021	1/2	2	Yes		NA/TC	R (15JUN2021)	N/N
			Injection site pain/ injection site pain#	4	14JUN2021	1/4	1	Yes		NA/TC	R (17JUN2021)	N/N
			Pain/ body aches#	4	14JUN2021	1/2	1	Yes		NA/TC	R (15JUN2021)	N/N
			Pyrexia/ fever#	4	14JUN2021	1/2	1	Yes		NA/TC	R (15JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1016 10161366/ Placebo	12/M/ WHITE	NERV	Headache/ headache#	4	14JUN2021	1/2	1	Yes		NA/TC	R (15JUN2021)	N/N
		GASTR	Vomiting/ vomiting#	4	08JUL2021	2/2	1	Yes		NA	R (09JUL2021)	N/N
C4591001 1016 10161371/ Placebo	12/F/ WHITE	GENRL	Fatigue/ fatigue#	4	15JUN2021	2/3	1	Yes		NA	R (17JUN2021)	N/N
C4591001 1039 10391246/ Placebo	15/M/ WHITE		Pyrexia/ fever, low grade#	4	15JUN2021	2/1	1	Yes		NA/TC	R (15JUN2021)	N/N
		GENRL	Fatigue/ fatigue#	3	27FEB2021	2/3	2	Yes		NA	R (01MAR2021)	N/N
			Pain/ generalized achiness#	3	27FEB2021	2/4	2	Yes		NA	R (02MAR2021)	N/N
			Pyrexia/ fever#	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
		NERV	Headache/ headache#	3	27FEB2021	2/3	1	Yes		NA	R (01MAR2021)	N/N
		GENRL	Fatigue/ fatigue#	4	19MAR2021	2/2	1	Yes		NA	R (20MAR2021)	N/N
C4591001 1039 10391250/	14/F/ WHITE		Pyrexia/ fever#	4	19MAR2021	2/2	1	Yes		NA	R (20MAR2021)	N/N
		PSYCH	Tic/ exacerbation of tic disorder	2	09JAN2021	13/C	1	No	O	NA	RG	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
BNT162b2 (30 µg)												
C4591001 1039 10391251/ Placebo	15/F/ ASIAN	GENRL	Fatigue/ Fatigue#	4	25FEB2021	1/3	1	Yes		NA	R (27FEB2021)	N/N
		NERV	Headache/ Headache#	4	25FEB2021	1/3	1	Yes		NA	R (27FEB2021)	N/N
C4591001 1039 10391258/ Placebo	13/F/ WHITE	GENRL	Pyrexia/ Fever#	4	01JUN2021	1/2	1	Yes		NA/TC	R (02JUN2021)	N/N
		NERV	Headache/ Headache#	4	01JUN2021	1/2	1	Yes		NA/TC	R (02JUN2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	02JUN2021	2/2	1	Yes		NA/TC	R (03JUN2021)	N/N
C4591001 1039 10391259/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ injection site pain#	3	14MAY2021	1/8	1	Yes		NA/TC	R (21MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	3	15MAY2021	2/1	1	Yes		NA/TC	R (15MAY2021)	N/N
		GENRL	Injection site pain/ injection site pain#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/Y
		GENRL	Pyrexia/ fever#	4	05JUN2021	2/3	1	Yes		NA/TC	R (07JUN2021)	N/N
		GENRL	Fatigue/ fatigue#	4	06JUN2021	3/1	1	Yes		NA/TC	R (06JUN2021)	N/N
		NERV	Headache/ headache#	4	06JUN2021	3/1	1	Yes		NA/TC	R (06JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1039 10391264/ Placebo	12/F/ ASIAN	MUSC	Myalgia/ General muscle aches#	3	25MAY2021	2/3	1	Yes		NA	R (27MAY2021)	N/N
C4591001 1039 10391266/ Placebo	12/M/ WHITE	GENRL	Fatigue/ Fatigue#	4	04JUN2021	2/2	1	Yes		NA	R (05JUN2021)	N/N
			Pain/ Body ache#	4	04JUN2021	2/2	1	Yes		NA/TC	R (05JUN2021)	N/N
			Pyrexia/ Fever - max 100F#	4	04JUN2021	2/2	1	Yes		NA/TC	R (05JUN2021)	N/N
		MUSC	Myalgia/ Left arm muscle ache#	4	04JUN2021	2/2	1	Yes		NA	R (05JUN2021)	N/N
C4591001 1039 10391268/ Placebo	13/F/ WHITE	GENRL	Pyrexia/ Fever - up to 102.5#	3	14MAY2021	2/2	3	Yes		NA	R (15MAY2021)	N/N
C4591001 1039 10391270/ Placebo	13/F/ WHITE	RESP	Epistaxis/ Epistaxis	1	23DEC2020	15/1	1	No	O	NA	R (23DEC2020)	N/N
		GENRL	Injection site pain/ Injection site pain#	3	13MAY2021	1/2	1	Yes		NA/TC	R (14MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	3	14MAY2021	2/3	1	Yes		NA	R (16MAY2021)	N/N
			Pyrexia/ Fever#	3	14MAY2021	2/1	1	Yes		NA/TC	R (14MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	4	04JUN2021	2/3	1	Yes		NA/TC	R (06JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1039 10391271/ Placebo	14/F/ WHITE	NERV	Pyrexia/ fever#	4	04JUN2021	2/2	1	Yes		NA/TC	R (05JUN2021)	N/N
			Headache/ Headache#	3	14MAY2021	2/1	2	Yes		NA/TC	R (14MAY2021)	N/N
		NERV	Headache/ headache#	4	04JUN2021	2/1	2	Yes		NA/TC	R (04JUN2021)	N/N
C4591001 1039 10391273/ Placebo	12/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	14MAY2021	2/1	1	Yes		NA	R (14MAY2021)	N/N
			Injection site pain/ Injection site soreness#	3	14MAY2021	2/2	1	Yes		NA	R (15MAY2021)	N/N
C4591001 1039 10391274/ Placebo	13/M/ WHITE	IMMUN	Food allergy/ exacerbation of pineapple food allergy#	4	01JUL2021	28/1	1	No	O	NA/TC	R (01JUL2021)	N/N
		RESP	Upper-airway cough syndrome/ post nasal drip#	4	01JUL2021	28/6	1	No	O	NA/TC	R (06JUL2021)	N/N
C4591001 1039 10391279/ Placebo	14/F/ WHITE	GENRL	Injection site pain/ injection site pain#	3	17MAY2021	1/3	1	Yes		NA/TC	R (19MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	3	18MAY2021	2/2	1	Yes		NA	R (19MAY2021)	N/N
		GENRL	Chills/ Chills#	4	07JUN2021	1/2	1	Yes		NA/TC	R (08JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1039 10391280/ Placebo	13/F/ WHITE	NERV	Fatigue/ Fatigue#	4	07JUN2021	1/2	1	Yes		NA/TC/TCN	R (08JUN2021)	N/N
			Injection site pain/ Injection site pain#	4	07JUN2021	1/2	1	Yes		NA	R (08JUN2021)	N/N
			Pain/ Body aches#	4	07JUN2021	1/2	1	Yes		NA/TC	R (08JUN2021)	N/N
			Presyncope/ Vasovagal episode	2	04FEB2021	29/1	1	No	O	NA	R (04FEB2021)	N/N
C4591001 1039 10391283/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Injection site soreness#	3	15MAY2021	2/4	1	Yes		NA	R (18MAY2021)	N/N
		GENRL	Injection site pain/ Injection site soreness#	3	13MAY2021	1/3	1	Yes		NA	R (15MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	14MAY2021	2/3	2	Yes		NA	R (16MAY2021)	N/N
C4591001 1039 10391285/ Placebo	13/F/ WHITE	NERV	Headache/ Headache#	3	14MAY2021	2/3	2	Yes		NA	R (16MAY2021)	N/N
		GASTR	Nausea/ nausea#	3	14MAY2021	1/2	1	Yes		NA	R (15MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	3	14MAY2021	1/2	1	Yes		NA	R (15MAY2021)	N/N
		GENRL	Injection site pain/ injection site pain#	3	15MAY2021	2/1	1	Yes		NA	R (15MAY2021)	N/N
		GASTR	Nausea/ nausea#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1039 10391287/ Placebo	14/F/ WHITE	GENRL	Pyrexia/ fever#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/N
		MUSC	Arthralgia/ Generalized Arthralgia##+	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/N
		GENRL	Myalgia/ muscle aches#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/N
		GENRL	Fatigue/ fatigue#	3	13MAY2021	1/2	1	Yes		NA	R (14MAY2021)	N/N
		GENRL	Injection site pain/ injection site pain#	3	14MAY2021	2/2	1	Yes		NA	R (15MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	4	03JUN2021	1/2	1	Yes		NA	R (04JUN2021)	N/N
		GENRL	Injection site pain/ injection site soreness#	4	04JUN2021	2/1	1	Yes		NA	R (04JUN2021)	N/N
C4591001 1039 10391290/ BNT162b2 (30 µg)	12/F/ WHITE	NERV	Headache/ headache#	4	04JUN2021	2/2	1	Yes		NA	R (05JUN2021)	N/N
C4591001 1039 10391292/ Placebo	13/F/ WHITE	NERV	Presyncope/ Vasovagal episode#	2	13JUL2021	187/1	2	No	O	NA	R (13JUL2021)	N/N
C4591001 1039 10391292/ Placebo	13/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	14MAY2021	1/3	1	Yes		NA	R (16MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
C4591001 1039 10391294/ Placebo	13/M/ ASIAN	GENRL	Injection site pain/ Injection site soreness#	3	14MAY2021	1/9	1	Yes		NA	R (22MAY2021)	N/N	
			GASTR	Nausea/ Nausea#	4	04JUN2021	1/3	1	Yes		NA/TC	R (06JUN2021)	N/N
			GENRL	Fatigue/ Fatigue#	4	04JUN2021	1/3	1	Yes		NA/TC	R (06JUN2021)	N/N
				Injection site pain/ Injection arm soreness#	4	04JUN2021	1/7	1	Yes		NA/TC	R (10JUN2021)	N/N
C4591001 1039 10391296/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ Injection site soreness#	3	14MAY2021	1/2	1	Yes		NA	R (15MAY2021)	N/N	
			GASTR	Nausea/ nausea#	4	04JUN2021	1/3	1	Yes		NA	R (06JUN2021)	N/N
			GENRL	Axillary pain/ Left armpit soreness#	4	04JUN2021	1/3	1	Yes		NA	R (06JUN2021)	N/N
				Chills/ Chills#	4	04JUN2021	1/2	1	Yes		NA/TC	R (05JUN2021)	N/N
	GENRL	Pyrexia/ Fever 102#	4	05JUN2021	2/1	2	Yes		NA/TC	R (05JUN2021)	N/N		

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1039 10391301/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Injection site pain#	3	13MAY2021	1/6	1	Yes		NA	R (18MAY2021)	N/N
		NERV	Presyncope/ vasovagal episode#	2	13MAY2021	113/1	1	No	O	NA	R (13MAY2021)	N/N
		MUSC	Myalgia/ General muscle aches#	3	14MAY2021	2/3	1	Yes		NA	R (16MAY2021)	N/N
		NERV	Headache/ Headache#	3	14MAY2021	2/3	1	Yes		NA	R (16MAY2021)	N/N
		GENRL	Chills/ chills#	4	05JUN2021	2/2	1	Yes		NA	R (06JUN2021)	N/N
			Injection site pain/ injection site soreness#	4	05JUN2021	2/4	1	Yes		NA	R (08JUN2021)	N/N
			Pain/ body aches#	4	05JUN2021	2/2	1	Yes		NA	R (06JUN2021)	N/N
			Pyrexia/ fever#	4	05JUN2021	2/2	1	Yes		NA	R (06JUN2021)	N/N
		NERV	Headache/ headache#	4	05JUN2021	2/2	1	Yes		NA	R (06JUN2021)	N/N
		C4591001 1039 10391303/ Placebo	13/M/ WHITE	GENRL	Chills/ chills#	4	04JUN2021	1/2	1	Yes		NA
C4591001 1039 10391305/ Placebo	13/M/ WHITE	GENRL	Fatigue/ Fatigue#	3	15MAY2021	2/2	1	Yes		NA	R (16MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1039 10391307/ Placebo	15/F/ WHITE	INJ&P	Muscle strain/ exacerbation of neck muscle strain#	3	14MAY2021	1/C	3	No	O	NA/TC	RG	N/N
		ENDO	Thyroid mass/ thyroid nodule#	3	01JUN2021	19/C	1	No	O	NA	N	N/N
		GENRL	Chills/ chills#	4	04JUN2021	1/3	2	Yes		NA/TC	R (06JUN2021)	N/N
			Injection site pain/ injection site soreness#	4	04JUN2021	1/4	2	Yes		NA	R (07JUN2021)	N/Y
			Pyrexia/ fever#	4	04JUN2021	1/3	1	Yes		NA/TC	R (06JUN2021)	N/N
		MUSC	Myalgia/ muscle aches#	4	04JUN2021	1/3	2	Yes		NA/TC	R (06JUN2021)	N/N
		NERV	Headache/ headache#	4	04JUN2021	1/3	2	Yes		NA/TC	R (06JUN2021)	N/N
		GASTR	Vomiting/ vomiting#	4	05JUN2021	2/2	1	Yes		NA	R (06JUN2021)	N/N
		METAB	Vitamin D deficiency/ Vitamin D deficiency#	4	11JUN2021	8/C	1	No	O	NA/TC	RG	N/N
		ENDO	Autoimmune thyroiditis/ Hashimoto's thyroiditis#	4	14JUN2021	11/C	1	No	O	NA	N	N/N
C4591001 1039 10391309/ Placebo	14/M/ ASIAN	GENRL	Fatigue/ fatigue#	2	17MAY2021	111/2	1	Yes		NA	R (18MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Cause of Vax Rel <sup>c</sup> AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1039 10391310/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ injection site pain#	2	17MAY2021	111/2	1	Yes	NA	R (18MAY2021)	N/N
			Fatigue/ fatigue#	4	09JUN2021	2/4	1	Yes	NA	R (12JUN2021)	N/N
			Fatigue/ fatigue#	2	14MAY2021	109/2	1	Yes	NA	R (15MAY2021)	N/N
			Injection site bruising/ bruise at injection site#	3	14MAY2021	1/5	1	Yes	NA	R (18MAY2021)	N/N
			NERV Headache/ headache#	2	14MAY2021	109/1	1	Yes	NA/TC	R (14MAY2021)	N/N
			GENRL Injection site swelling/ swelling at injection site#	3	18MAY2021	5/14	1	Yes	NA	R (31MAY2021)	N/N
			GENRL Injection site bruising/ bruising at injection site#	4	07JUN2021	1/8	1	Yes	NA	R (14JUN2021)	N/N
			GENRL Fatigue/ fatigue#	4	08JUN2021	2/2	1	Yes	NA	R (09JUN2021)	N/N
C4591001 1039 10391313/ Placebo	14/M/ WHITE	GENRL	NERV Headache/ headache#	4	08JUN2021	2/2	1	Yes	NA/TC	R (09JUN2021)	N/N
			Pain/ General Body aches#	3	15MAY2021	2/1	2	Yes	NA/TC	R (15MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1039 10391314/ Placebo	14/F/ ASIAN	GENRL	Injection site pain/ Injection site soreness#	4	03JUN2021	1/3	1	Yes		NA	R (05JUN2021)	N/N
			Pain/ General Body aches#	4	03JUN2021	1/3	2	Yes		NA/TC	R (05JUN2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	04JUN2021	2/2	2	Yes		NA	R (05JUN2021)	N/N
C4591001 1039 10391315/ BNT162b2 (30 µg)	14/M/ WHITE	NEOPL	Fibroadenoma of breast/ Exacerbation of fibroadenoma of right breast	2	06FEB2021	10/60	1	No	O	NA/TCN	R (06APR2021)	N/N
C4591001 1039 10391315/ BNT162b2 (30 µg)	14/M/ WHITE	NERV	Injection site pain/ Injection Site Pain#	3	17MAY2021	1/3	1	Yes		NA	R (19MAY2021)	N/N
C4591001 1039 10391317/ Placebo	12/M/ ASIAN	NERV	Presyncope/ vasovagal episode#	2	22JUL2021	177/1	2	No	O	NA	R (22JUL2021)	N/N
C4591001 1039 10391317/ Placebo	12/M/ ASIAN	GASTR	Vomiting/ vomiting*		07JAN2021	1/1	1	No	O	NA	R (07JAN2021)	N/N
		NERV	Presyncope/ pre-syncope*		07JAN2021	1/1	1	No	O	NA	R (07JAN2021)	N/N
		GENRL	Chills/ chills#	3	15MAY2021	2/1	1	Yes		NA/TC	R (15MAY2021)	N/N
			Fatigue/ fatigue#	3	15MAY2021	2/1	1	Yes		NA	R (15MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1039 10391319/ Placebo	12/M/ WHITE	GENRL	Chills/ chills#	3	21MAY2021	2/2	2	Yes		NA/TC	R (22MAY2021)	N/N
			Injection site pain/ injection site pain#	3	21MAY2021	2/3	2	Yes		NA/TC	R (23MAY2021)	N/N
			Pyrexia/ fever - max temp 102.3#	3	21MAY2021	2/3	3	Yes		NA/TC	R (23MAY2021)	N/N
C4591001 1039 10391321/ Placebo	12/F/ WHITE	GENRL	Chills/ Chills#	3	17MAY2021	1/2	2	Yes		NA/TC	R (18MAY2021)	N/N
		GENRL	Injection site pain/ Injection arm soreness#	4	08JUN2021	1/2	1	Yes		NA/TC	R (09JUN2021)	N/N
C4591001 1039 10391325/ Placebo	13/F/ ASIAN	GENRL	Chills/ Chills#	3	13MAY2021	1/3	2	Yes		NA/TC	R (15MAY2021)	N/N
			Fatigue/ fatigue#	3	13MAY2021	1/3	2	Yes		NA	R (15MAY2021)	N/N
			Pyrexia/ Fever - up to 103.4#	3	13MAY2021	1/2	3	Yes		NA/TC	R (14MAY2021)	N/N
		GENRL	Chills/ chills#	4	03JUN2021	1/3	1	Yes		NA/TC	R (05JUN2021)	N/N
			Fatigue/ fatigue#	4	03JUN2021	1/2	1	Yes		NA	R (04JUN2021)	N/N
		GENRL	Fatigue/ fatigue#	4	04JUN2021	2/4	2	Yes		NA	R (07JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
C4591001 1039 10391326/ BNT162b2 (30 µg)	15/M/ ASIAN	PSYCH	Injection site bruising/ bruise at injection site#	4	04JUN2021	2/8	1	Yes		NA	R (11JUN2021)	N/N	
			Pain/ generalized aches#	4	04JUN2021	2/2	1	Yes		NA/TC	R (05JUN2021)	N/N	
			Depression/ Depression Exacerbation	1	26JAN2021	16/5	3	No	O	NA/TC/TCN	R (30JAN2021)	Y/N	
C4591001 1039 10391327/ Placebo	15/M/ WHITE	PSYCH	Depression/ Depression Exacerbation	2	29MAR2021	57/5	3	No	O	NA/TC/TCN	R (02APR2021)	Y/N	
			GENRL	Fatigue/ Fatigue#	2	06JUN2021	126/3	1	Yes		NA	R (08JUN2021)	N/N
C4591001 1039 10391328/ Placebo	14/F/ WHITE	GENRL	Fatigue/ fatigue#	3	14MAY2021	1/4	1	Yes		NA	R (17MAY2021)	N/N	
			GENRL	Injection site pain/ Injection site pain#	3	14MAY2021	1/4	1	Yes		NA/TC	R (17MAY2021)	N/N
			GENRL	Fatigue/ Fatigue#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/N
			Injection site pain/ Injection arm soreness#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/N	

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1039 10391329/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ Injection site soreness#	3	21MAY2021	2/3	1	Yes		NA	R (23MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	4	11JUN2021	2/3	1	Yes		NA	R (13JUN2021)	N/N
			Injection site pain/ injection arm soreness#	4	11JUN2021	2/3	1	Yes		NA	R (13JUN2021)	N/N
C4591001 1039 10391330/ BNT162b2 (30 µg)	15/M/ WHITE	GASTR	Abdominal pain upper/ stomach pain#	2	25JUN2021	144/1	1	No	O	NA	R (25JUN2021)	N/N
			Nausea/ nausea#	2	25JUN2021	144/1	1	No	O	NA	R (25JUN2021)	N/N
C4591001 1039 10391332/ BNT162b2 (30 µg)	13/F/ WHITE	PSYCH	Suicidal ideation/ Active Suicidal Ideation	2	12APR2021	70/10	4	No	O	NA/TC/TCN	R (21APR2021)	Y/N
C4591001 1039 10391333/ Placebo	15/M/ WHITE	GENRL	Fatigue/ fatigue#	4	12JUN2021	2/2	1	Yes		NA	R (13JUN2021)	N/N
C4591001 1039 10391337/ Placebo	15/M/ WHITE	SKIN	Urticaria/ urticaria, both hands	2	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N
		GENRL	Chills/ chills#	3	14MAY2021	1/2	2	Yes		NA/TC	R (15MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1039 10391339/ Placebo	12/F/ WHITE	GASTR	Vomiting/ vomit#	3	15MAY2021	2/1	1	Yes		NA/TC	R (15MAY2021)	N/N
		GENRL	Pyrexia/ Fever#	4	05JUN2021	2/2	1	Yes		NA/TC	R (06JUN2021)	N/N
		GASTR	Nausea/ Nausea	1	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N
C4591001 1044 10441265/ Placebo	14/M/ WHITE	INFEC	Vomiting/ Vomiting Sinusitis/ sinusitis#	1 4	12JAN2021 16JUN2021	1/1 8/12	1 1	Yes No		NA O NA/TC	R (12JAN2021) R (27JUN2021)	N/N N/N
C4591001 1044 10441266/ BNT162b2 (30 µg)	14/F/ WHITE	SKIN	Acne/ Worsening of acne	2	07JAN2021	11/26	1	No	O	NA/TC	R (01FEB2021)	N/N
C4591001 1044 10441267/ Placebo	14/M/ WHITE	INJ&P	Fall/ Accidental fall	2	29APR2021	123/35	2	No	O	NA/TC	R (02JUN2021)	N/N
C4591001 1044 10441275/ Placebo	12/F/ WHITE	MUSC	Hand fracture/ thumb fracture Myalgia/ myalgia	2 2	29APR2021 04JAN2021	123/35 7/1	2 1	No Yes	O	NA/TC NA/TC	R (02JUN2021) R (04JAN2021)	N/N N/N
C4591001 1044	15/M/ WHITE	GENRL	Injection site pain/ injection site pain#	4	25MAR2021	2/1	1	Yes		NA	R (25MAR2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
10441282/ Placebo												
C4591001 1044 10441284/ Placebo	15/M/ WHITE	PSYCH	Depression/ depression	2	01FEB2021	35/C	1	No	O	NA/TC	RG	N/N
		PSYCH	Anxiety/ Anxiety	2	27APR2021	120/C	2	No	O	NA/TC	RG	N/N
C4591001 1044 10441285/ BNT162b2 (30 µg)	15/F/ WHITE	SURG	Wisdom teeth removal/ Wisdom teeth extraction	2	22JUN2021	175/1	2	No	O	NA	R (22JUN2021)	N/N
C4591001 1044 10441292/ Placebo	15/M/ WHITE	GENRL	Oedema peripheral/ Edema Toes (Bilateral)	1	17DEC2020	1/3	1	No	O	NA/TC	R (19DEC2020)	N/N
C4591001 1044 10441300/ BNT162b2 (30 µg)	15/M/ WHITE	GASTR	Abdominal pain upper/ Stomach pain#	2	31AUG2021	226/2	1	No	O	NA	R (01SEP2021)	N/N
C4591001 1044 10441303/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Injection site pain#	3	20APR2021	1/4	1	Yes		NA	R (23APR2021)	N/N
		MUSC	Myalgia/ generlized Muscle aches#	3	20APR2021	1/3	1	Yes		NA	R (22APR2021)	N/N
C4591001 1044	15/F/ WHITE	SKIN	Rash/ generalized rash	2	25FEB2021	38/3	1	No	O	NA/TC	R (27FEB2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
10441304/ BNT162b2 (30 µg)												
C4591001 1044 10441309/ BNT162b2 (30 µg)	12/M/ WHITE	EYE	Eye pain/ Ocular Pain in Right Eye	2	12MAY2021	115/3	2	No	O	NA	R (14MAY2021)	N/N
C4591001 1044 10441320/ Placebo	15/M/ WHITE	GENRL	Chills/ chills#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/N
		NERV	Headache/ headache#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/N
C4591001 1044 10441328/ BNT162b2 (30 µg)	15/F/ WHITE	INFEC	Pilonidal cyst/ Pilonidal cyst	2	22APR2021	87/C	2	No	O	NA/TCN	RG	N/N
C4591001 1044 10441335/ Placebo	15/F/ WHITE	SKIN	Acne/ Worsening of acne	2	27FEB2021	30/C	1	No	O	NA/TC	RG	N/N
C4591001 1044 10441337/ Placebo	13/M/ WHITE	INJ&P	Humerus fracture/ Broken humerus (right arm)	1	10JAN2021	3/34	2	No	O	NA/TC	R (12FEB2021)	N/N
C4591001 1044 10441338/ Placebo	13/F/ WHITE	NEOPL	Skin papilloma/ Wart on second toe (left)	2	01FEB2021	4/7	1	No	O	NA/TC	R (07FEB2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1044 10441345/ Placebo	12/F/ WHITE	GASTR	Nausea/ nausea#	4	07JUN2021	1/2	1	Yes		NA/TC	R (08JUN2021)	N/N
			Vomiting/ vomitting#	4	07JUN2021	1/2	1	Yes		NA	R (08JUN2021)	N/N
		MUSC	Myalgia/ generalized myalgia#	4	07JUN2021	1/C	2	Yes		NA/TC	RG	N/N
		NERV	Dizziness/ dizziness#	4	07JUN2021	1/1	2	Yes		NA	R (07JUN2021)	N/N
C4591001 1044 10441351/ Placebo	15/M/ WHITE	INJ&P	Muscle strain/ Left hip flexor strain	2	11FEB2021	11/17	2	No	O	NA/TC	R (27FEB2021)	N/N
C4591001 1044 10441354/ Placebo	13/F/ WHITE	PSYCH	Attention deficit hyperactivity disorder/ Worsening of ADHD	2	24APR2021	86/C	1	No	O	NA/TC	N	N/N
C4591001 1044 10441361/ BNT162b2 (30 µg)	15/M/ WHITE	INJ&P	Concussion/ Concussion	1	23JAN2021	13/22	1	No	O	NA	R (13FEB2021)	N/N
		SKIN	Dermatitis contact/ allergic contact dermatitis involving all extremities (contact with poison sumac)	2	24APR2021	81/C	1	No	O	NA/TC	RG	N/N

16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age													
Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
C4591001 1044 10441364/ BNT162b2 (30 µg)	15/F/ WHITE	PSYCH	Attention deficit hyperactivity disorder/ attention deficit hyperactivity disorder	2	29APR2021	86/	1	No	O	NA/TC	R	N/N	
		CARD	Tachycardia/ Tachycardia#	2	19AUG2021	198/C	1	No	O	NA	RG	N/N	
		NERV	Dizziness/ Lightheadedness#	2	19AUG2021	198/C	1	No	O	NA	RG	N/N	
C4591001 1044 10441373/ Placebo	14/F/ WHITE	SKIN	Urticaria/ hives forehead	1	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N	
		PSYCH	Anxiety/ Worsening of Anxiety	2	05MAR2021	30/C	2	No	O	NA/TC	RG	N/N	
C4591001 1044 10441384/ Placebo	13/M/ WHITE	MUSC	Tendonitis/ Achilles tendinitis	2	08MAR2021	33/C	2	No	O	NA/TC	RG	N/N	
		RESP	Nasal congestion/ nasal congestion	2	07MAY2021	93/C	1	No	O	NA/TC	RG	N/N	
C4591001 1057 10571387/ Placebo	14/F/ WHITE	MUSC	Pain in extremity/ ARM SORENESS#	4	23JUN2021	1/2	1	Yes		NA	R (24JUN2021)	N/N	
C4591001 1057 10571389/ Placebo	12/F/ WHITE	GENRL	Fatigue/ FATIGUE#	2	24MAY2021	141/1	1	Yes		NA	R (24MAY2021)	N/N	

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1057 10571407/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ LEFT ARM INJECTION SITE SORNESS#	2	24MAY2021	141/1	1	Yes		NA	R (24MAY2021)	N/N
			Fatigue/ FATIGUE#	4	02APR2021	1/3	1	Yes		NA	R (04APR2021)	N/N
			Injection site pain/ RIGHT ARM INJECTION SITE SORENESS#	4	02APR2021	1/3	1	Yes		NA	R (04APR2021)	N/N
C4591001 1057 10571408/ Placebo	14/M/ WHITE	GASTR	Nausea/ NAUSEA#	3	25MAY2021	1/2	1	Yes		NA	R (26MAY2021)	N/N
			NERV Headache/ HEADACHE#	3	25MAY2021	1/2	1	Yes		NA	R (26MAY2021)	N/N
C4591001 1057 10571431/ Placebo	13/M/ WHITE	GENRL	Pain/ BODY ACHES#	4	21JUN2021	1/3	1	Yes		NA	R (23JUN2021)	N/N
C4591001 1057 10571432/ Placebo	12/F/ WHITE	GENRL	Fatigue/ FATIGUE#	4	01JUN2021	1/2	1	Yes		NA	R (02JUN2021)	N/N
			Injection site pain/ LEFT ARM INJECTION SITE SORENESS#	4	01JUN2021	1/2	1	Yes		NA	R (02JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1057 10571434/ Placebo	13/M/ MULTIPLE	GENRL	Injection site pain/ PAIN AT INJECTION SITE LEFT DELTOID#	4	29JUN2021	1/3	1	Yes		NA	R (01JUL2021)	N/N
		MUSC	Pain in extremity/ LEFT UPPER ARM PAIN#	4	29JUN2021	1/3	1	Yes		NA	R (01JUL2021)	N/N
C4591001 1057 10571441/ Placebo	13/M/ ASIAN	MUSC	Myalgia/ MUSCLE ACHES#	4	09JUN2021	1/3	1	Yes		NA	R (11JUN2021)	N/N
C4591001 1057 10571451/ BNT162b2 (30 µg)	12/F/ WHITE	INFEC	Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	1	13JAN2021	2/22	2	No	O	NA/TC	R (03FEB2021)	N/N
C4591001 1066 10661410/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ pain at injection site#	4	09JUN2021	2/3	1	Yes		NA	R (11JUN2021)	N/N
C4591001 1066 10661422/ BNT162b2 (30 µg)	12/M/ WHITE	SKIN	Rash/ rash on torso	1	24DEC2020	3/5	1	No	O	NA	R (28DEC2020)	N/N
C4591001 1077 10771275/ Placebo	13/M/ WHITE	INJ&P	Fall/ FALL	2	07MAY2021	137/1	1	No	O	NA	R (07MAY2021)	N/N
			Ligament sprain/ RIGHT WRIST SPRAIN	2	07MAY2021	137/19	1	No	O	NA/TC	R (25MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1077 10771278/ BNT162b2 (30 µg)	13/M/ WHITE	GASTR	Diarrhoea/ DIARRHEA	2	23DEC2020	1/2	2	Yes		NA	R (24DEC2020)	N/N
			Vomiting/ VOMITING	2	23DEC2020	1/1	1	Yes		NA	R (23DEC2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	23DEC2020	1/2	2	Yes		NA	R (24DEC2020)	N/N
			Injection site pain/ RIGHT ARM INJECTION SITE PAIN	2	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
		Injection site swelling/ INJECTION SITE SWELLING	2	23DEC2020	1/2	2	Yes		NA	R (24DEC2020)	N/N	
		Pyrexia/ FEVER	2	23DEC2020	1/2	3	Yes		NA/TC	R (24DEC2020)	N/N	
		PSYCH	Disorientation/ DISORIENTATION	2	23DEC2020	1/1	2	Yes		NA	R (23DEC2020)	N/N
		C4591001 1077 10771279/ BNT162b2 (30 µg)	13/M/ WHITE	GASTR	Oral mucosal blistering/ ORAL/BUCCAL BLISTERS	2	07JAN2021	4/4	2	Yes		NA
INJ&P	Hand fracture/ RIGHT 5TH METACARPAL FRACTURE#			2	18MAY2021	135/30	1	No	O	NA	R (16JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1077 10771280/ Placebo	14/F/ WHITE	INJ&P	Concussion/ CONCUSSION	2	08APR2021	95/14	1	No	O	NA	R (21APR2021)	N/N
			Fall/ FALL	2	08APR2021	95/1	1	No	O	NA	R (08APR2021)	N/N
C4591001 1077 10771285/ Placebo	14/F/ WHITE	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	19MAY2021	2/3	1	Yes		NA/TC	R (21MAY2021)	N/N
C4591001 1077 10771295/ Placebo	15/M/ WHITE	INJ&P	Ligament rupture/ RIGHT KNEE ACL TEAR#	4	29MAR2021	13/29	2	No	O	NA/TCN	R (26APR2021)	N/N
			Meniscus injury/ RIGHT KNEE MENISCUS TEAR#	4	29MAR2021	13/29	2	No	O	NA	R (26APR2021)	N/N
			Sports injury/ FOOTBALL INJURY#	4	29MAR2021	13/1	2	No	O	NA	R (29MAR2021)	N/N
C4591001 1077 10771298/ Placebo	14/M/ WHITE	GENRL	Fatigue/ FATIGUE#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/N
C4591001 1077 10771300/ BNT162b2 (30 µg)	15/F/ WHITE	REPRO	Amenorrhoea/ AMENORRHEA	1	12JAN2021	6/80	1	No	O	NA	R (01APR2021)	N/N
C4591001 1084	15/F/ WHITE	INFEC	Ear infection/ L Ear infection	2	28JAN2021	11/9	2	No	O	NA/TC	R (05FEB2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
10841556/ BNT162b2 (30 µg)												
C4591001 1084 10841558/ BNT162b2 (30 µg)	15/F/ WHITE	INJ&P	Ligament sprain/ left sprained ankle	2	27JAN2021	10/2	2	No	O	NA/TC	R (28JAN2021)	N/N
C4591001 1084 10841560/ Placebo	15/M/ WHITE	PSYCH	Obsessive- compulsive disorder/ Obsessive compulsive disorder	2	09FEB2021	19/C	2	No	O	NA/TC	N	N/N
C4591001 1084 10841569/ Placebo	14/F/ WHITE	NERV	Headache/ Headache	2	29JAN2021	8/15	1	No	O	NA	R (12FEB2021)	N/N
C4591001 1091 10911406/ BNT162b2 (30 µg)	14/M/ WHITE	PSYCH	Panic attack/ Panic attacks	2	25FEB2021	60/C	2	No	O	NA	N	N/N
C4591001 1091 10911411/ Placebo		INJ&P	Upper limb fracture/ Broken right arm	2	25MAY2021	149/C	3	No	O	NA/TCN	RG	N/N
C4591001 1091 10911411/ Placebo	15/M/ WHITE	GASTR	Tooth impacted/ Tooth impaction#	4	15JUL2021	22/1	2	No	O	NA	R (15JUL2021)	N/N
C4591001 1091 10911414/ BNT162b2 (30 µg)	14/M/ WHITE	GENRL	Injection site pain/ Injection site pain#	2	26MAY2021	2/2	1	Yes		NA	R (27MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1091 10911417/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ Injection site pain left arm#	3	18MAY2021	1/1	1	Yes		NA	R (18MAY2021)	N/N
			Pyrexia/ Fever#	3	18MAY2021	1/1	1	Yes		NA/TC	R (18MAY2021)	N/N
C4591001 1091 10911422/ BNT162b2 (30 µg)	15/F/ WHITE	INFEC	Ear infection/ left ear infection	1	23DEC2020	10/8	1	No	O	NA/TC	R (30DEC2020)	N/N
			Otitis externa/ outer ear infection left ear	1	23DEC2020	10/8	1	No	O	NA/TC	R (30DEC2020)	N/N
			Otitis media/ middle ear infection left ear	1	23DEC2020	10/8	1	No	O	NA/TC	R (30DEC2020)	N/N
C4591001 1091 10911423/ Placebo	14/F/ BLACK OR AFRICAN AMERICAN	GASTR	Diarrhoea/ Diarrhea#	4	22JUL2021	2/2	1	Yes		NA	R (23JUL2021)	N/N
			Vomiting/ Vomitting#	4	22JUL2021	2/2	1	Yes		NA	R (23JUL2021)	N/N
		MUSC	Myalgia/ Myalgia#	4	22JUL2021	2/2	1	Yes		NA	RS (23JUL2021)	N/N
		NERV	Headache/ Headache#	4	22JUL2021	2/2	1	Yes		NA	R (23JUL2021)	N/N
C4591001 1091 10911433/ Placebo	14/M/ WHITE	SKIN	Rash/ intermittent rash on wrist	1	19DEC2020	3/C	1	No	O	NA	N	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1091 10911447/ BNT162b2 (30 µg)	15/M/ WHITE	INFEC	Appendicitis/ Appendicitis#	2	09JUL2021	177/2	2	No	O	NA/TCN	R (10JUL2021)	Y/N
C4591001 1091 10911463/ Placebo	15/M/ WHITE	GASTR	Tooth impacted/ Wisdom teeth impaction	2	27APR2021	91/11	1	No	O	NA/TCN	R (07MAY2021)	N/N
C4591001 1123 11231440/ BNT162b2 (30 µg)	13/M/ WHITE	INFEC	Otitis media/ Left otitis media#	2	13AUG2021	229/9	2	No	O	NA/TC	R (21AUG2021)	N/N
C4591001 1123 11231442/ Placebo	12/M/ WHITE	NERV	Headache/ headache	1	16DEC2020	8/2	1	No	O	NA/TC	R (17DEC2020)	N/N
		PSYCH	Depression/ Depression	1	23DEC2020	15/164	2	No	O	NA/TC	R (04JUN2021)	N/N
		PSYCH	Depression/ worsening of depression	2	MAR2021	57/	1	No	O	NA/TC	R (04JUN2021)	N/N
C4591001 1123 11231448/ Placebo	13/M/ BLACK OR AFRICAN AMERICAN	GASTR	Diarrhoea/ Diarrhea	1	16DEC2020	6/3	1	Yes		NA	R (18DEC2020)	N/N
C4591001 1123 11231472/ BNT162b2 (30 µg)	15/F/ WHITE	INFEC	Tinea capitis/ Tinea capitis	1	01JAN2021	12/43	1	No	O	NA/TC	R (12FEB2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		SKIN	Acne/ worsening of acne vulgaris	1	07JAN2021	18/C	1	No	O	NA/TC	N	N/N
C4591001 1123 11231473/ Placebo	15/F/ WHITE	INJ&P	Hand fracture/ avulsion fracture right middle finger	2	11APR2021	90/C	2	No	O	NA/TC/TCN	RG	N/N
C4591001 1123 11231489/ BNT162b2 (30 µg)	13/M/ WHITE	INJ&P	Meniscus injury/ Torn medial and lateral left knee menisci	2	MAR2021	50/C	1	No	O	NA/TC	RG	N/N
C4591001 1123 11231507/ BNT162b2 (30 µg)	14/F/ WHITE	PSYCH	Depression/ Worsening of Depression	2	19JAN2021	2/5	2	No	O	NA/TC	R (23JAN2021)	Y/N
		PSYCH	Attention deficit hyperactivity disorder/ WORSENING Attention Deficit Hyper Activity Disorder	2	01MAR2021	43/C	1	No	O	NA/TC	N	N/N
C4591001 1123 11231520/ Placebo	12/M/ WHITE	INFEC	Conjunctivitis/ Bilateral conjunctivitis	1	12JAN2021	14/6	1	No	O	NA/TC	R (17JAN2021)	N/N
C4591001 1123 11231523/ Placebo	12/M/ WHITE	EYE	Retinal haemorrhage/ INTRA RETINAL	2	16FEB2021	22/C	2	No	O	NA	RG	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
HEMORRHAGE OD												
C4591001 1124 11241245/ BNT162b2 (30 µg)	14/F/ WHITE	PSYCH	Anxiety/ Anxiety	2	MAR2021	55/C	2	No	O	NA/TC	RG	N/N
			Depression/ Depression	2	MAR2021	55/C	2	No	O	NA/TC	RG	N/N
C4591001 1124 11241251/ BNT162b2 (30 µg)	15/F/ WHITE	GENRL	Pyrexia/ Fever (102.2 degrees F)	2	09JAN2021	2/1	3	Yes		NA/TC	R (09JAN2021)	N/N
C4591001 1125 11251248/ Placebo	15/M/ WHITE	GENRL	Fatigue/ Fatigue	2	05JAN2021	7/4	1	Yes		NA/TC	R (08JAN2021)	N/N
C4591001 1126 11261233/ Placebo	14/M/ WHITE	GENRL	Fatigue/ Fatigue#	3	19MAY2021	1/2	1	Yes		NA	R (20MAY2021)	N/N
			Injection site pain/ Left Upper Arm Injection Site Pain#	3	19MAY2021	1/3	2	Yes		NA	R (21MAY2021)	N/N
		MUSC	Myalgia/ Muscle Aches#	3	20MAY2021	2/2	2	Yes		NA	R (21MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	09JUN2021	1/4	2	Yes		NA	R (12JUN2021)	N/N
C4591001 1126	12/F/ WHITE	SKIN	Photosensitivity reaction/	3	23MAY2021	6/4	2	No	O	NA/TC/TCN	R (26MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
11261235/ Placebo			Phyto photodermatitis, bilateral hands#									
		GENRL	Pain/ Generalized body aches#	4	09JUN2021	2/1	1	Yes	NA/TC		R (09JUN2021)	N/N
			Pyrexia/ Fever#	4	09JUN2021	2/1	1	Yes	NA/TC		R (09JUN2021)	N/N
C4591001 1126 11261239/ Placebo	15/F/ WHITE	GENRL	Injection site pain/ Left arm injection site pain#	3	17MAY2021	1/3	2	Yes	NA		R (19MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	07JUN2021	1/2	2	Yes	NA		R (08JUN2021)	N/N
			Injection site pain/ Pain, injection site#	4	07JUN2021	1/2	2	Yes	NA		R (08JUN2021)	N/N
			Pain/ Generalized body aches#	4	07JUN2021	1/2	2	Yes	NA		R (08JUN2021)	N/N
			Pyrexia/ Fever#	4	07JUN2021	1/2	2	Yes	NA/TC		R (08JUN2021)	N/N
C4591001 1126 11261240/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Pain, injection site#	3	21MAY2021	1/2	2	Yes	NA		R (22MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	10JUN2021	1/2	1	Yes	NA		R (11JUN2021)	N/N
			Injection site pain/ Pain, injection site#	4	10JUN2021	1/2	1	Yes	NA		R (11JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Pain/ Generalized body aches#	4	10JUN2021	1/2	1	Yes		NA	R (11JUN2021)	N/N
C4591001 1126 11261246/ BNT162b2 (30 µg)	13/M/ WHITE	MUSC	Pain in extremity/ Right leg pain	2	31DEC2020	9/C	1	No	O	NA	N	N/N
		GASTR	Aphthous ulcer/ Canker sore under tongue	2	12JAN2021	21/4	1	No	O	NA	R (15JAN2021)	N/N
		GENRL	Nodule/ Red bump on right index finger at cuticle	2	13JAN2021	22/50	1	No	O	NA	R (03MAR2021)	N/N
C4591001 1126 11261250/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ Pain, Injection Site#	3	19MAY2021	1/2	1	Yes		NA	R (20MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	15JUN2021	1/2	1	Yes		NA	R (16JUN2021)	N/N
			Injection site pain/ Pain, injection site#	4	15JUN2021	1/2	1	Yes		NA	R (16JUN2021)	N/N
C4591001 1126 11261253/ Placebo	13/M/ WHITE	GENRL	Chills/ Chills#	3	17MAY2021	1/1	2	Yes		NA	R (17MAY2021)	N/N
			Injection site pain/ Left arm injection site pain#	3	17MAY2021	1/3	1	Yes		NA/TC	R (19MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261254/ Placebo	15/M/ WHITE	MUSC	Myalgia/ Muscle aches#	3	17MAY2021	1/3	2	Yes		NA/TC	R (19MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	18MAY2021	2/2	2	Yes		NA	R (19MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	08JUN2021	1/2	1	Yes		NA	R (09JUN2021)	N/N
		IMMUN	Food allergy/ Allergic reaction, nuts	1	09DEC2020	7/1	2	No	O	NA/TC	R (09DEC2020)	N/N
		GENRL	Chills/ Chills#	3	23JUN2021	2/1	1	Yes		NA	R (23JUN2021)	N/N
			Injection site pain/ Injection site pain#	3	23JUN2021	2/3	1	Yes		NA	R (25JUN2021)	N/N
			Malaise/ Malaise#	3	23JUN2021	2/1	1	Yes		NA	R (23JUN2021)	N/N
C4591001 1126 11261262/ Placebo	15/F/ WHITE	NERV	Headache/ Headache#	3	23JUN2021	2/1	1	Yes		NA	R (23JUN2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	12JUL2021	1/2	1	Yes		NA	R (13JUL2021)	N/N
		NERV	Headache/ Headache#	4	12JUL2021	1/2	1	Yes		NA	R (13JUL2021)	N/N
		GENRL	Injection site pain/ Left upper arm injection site pain#	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
		GENRL	Malaise/ Malaise#	4	03MAR2021	1/2	2	Yes		NA	R (04MAR2021)	N/N
	NERV	Headache/ Headache#	4	03MAR2021	1/2	1	Yes		NA	R (04MAR2021)	N/N	

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261263/ BNT162b2 (30 µg)	15/M/ WHITE	GENRL	Injection site pain/ Injection site pain#	4	04MAR2021	2/3	1	Yes		NA	R (06MAR2021)	N/N
		BLOOD	Lymphadenopathy/ LEFT AXILLA LYMPH NODE SWELLING	1	10DEC2020	7/4	1	Yes		NA	R (13DEC2020)	N/N
		INJ&P	Fall/ Mechanical Fall	1	20DEC2020	17/1	2	No	O	NA	R (20DEC2020)	N/N
			Radius fracture/ RIGHT DISTAL RADIUS TORUS FRACTURE	1	20DEC2020	17/32	2	No	O	NA/TC	R (20JAN2021)	N/N
C4591001 1126 11261265/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Pain, injection site#	3	20MAY2021	2/4	1	Yes		NA	R (23MAY2021)	N/N
C4591001 1126 11261266/ Placebo	12/F/ WHITE	GENRL	Injection site pain/ Pain, injection site#	4	14JUN2021	1/2	1	Yes		NA	R (15JUN2021)	N/N
		GENRL	Injection site pain/ Pain, Injection site#	3	19MAY2021	1/2	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1126 11261267/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ Pain, injection site#	4	15JUN2021	2/1	1	Yes		NA	R (15JUN2021)	N/N
		GENRL	Injection site pain/ Left upper arm injection site pain#	3	21MAY2021	1/3	2	Yes		NA/TC	R (23MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	22MAY2021	2/1	2	Yes		NA	R (22MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
C4591001 1126 11261268/ BNT162b2 (30 µg)	13/F/ WHITE	SKIN	GENRL	Fatigue/ Fatigue#	4	11JUN2021	1/3	2	Yes		NA	R (13JUN2021)	N/N
				Injection site pain/ PAIN, INJECTION SITE#	4	11JUN2021	1/3	2	Yes		NA/TC	R (13JUN2021)	N/N
				Pain/ GENERALIZED BODY ACHES#	4	11JUN2021	1/3	2	Yes		NA/TC	R (13JUN2021)	N/N
				Pyrexia/ Fever#	4	11JUN2021	1/2	2	Yes		NA/TC	R (12JUN2021)	N/N
C4591001 1126 11261270/ Placebo	15/M/ WHITE	MUSC	SKIN	Urticaria/ Facial Urticaria, worsening	1	18DEC2020	5/14	1	No	O	NA	R (31DEC2020)	N/N
				Osteochondrosis/ Juvenile Osteochondrosis of bilateral fifth metatarsals	1	28DEC2020	15/C	2	No	O	NA/TC/TCN	RG	N/N
C4591001 1126 11261271/ BNT162b2 (30 µg)	15/M/ WHITE	INV	GENRL	Injection site pain/ Left upper arm injection site pain#	2	20MAY2021	135/2	1	Yes		NA	R (21MAY2021)	N/N
				Fatigue/ Fatigue#	4	11JUN2021	2/2	1	Yes		NA	R (12JUN2021)	N/N
				SARS-CoV-2 antibody test positive/ SARS-COV-2 IGG, QL, IA - Positive	2	21JAN2021	16/C	1	Yes		NA	N	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261274/ Placebo	15/F/ WHITE	GENRL	Injection site pain/ Left upper arm injection site pain#	3	20MAY2021	1/3	2	Yes		NA/TC	R (22MAY2021)	N/N
		NERV	Headache/ Headache#	3	21MAY2021	2/1	2	Yes		NA/TC	R (21MAY2021)	N/N
		GENRL	Injection site pain/ Pain, injection site#	4	11JUN2021	2/3	1	Yes		NA	R (13JUN2021)	N/N
C4591001 1126 11261275/ Placebo	15/F/ WHITE	GENRL	Injection site pain/ Left upper arm injection site pain#	3	08FEB2021	1/3	1	Yes		NA/TC	R (10FEB2021)	N/N
		GENRL	Chills/ Chills#	3	09FEB2021	2/1	2	Yes		NA/TC	R (09FEB2021)	N/N
		NERV	Headache/ Headache#	3	09FEB2021	2/1	2	Yes		NA/TC	R (09FEB2021)	N/N
C4591001 1126 11261276/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Left upper arm injection site pain#	3	08FEB2021	1/3	2	Yes		NA/TC	R (10FEB2021)	N/N
		GENRL	Pyrexia/ Fever#	3	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N
		NERV	Headache/ Headache#	3	09FEB2021	2/1	2	Yes		NA/TC	R (09FEB2021)	N/N
		GENRL	Malaise/ Malaise#	4	03MAR2021	1/2	1	Yes		NA	R (04MAR2021)	N/N
		NERV	Headache/ Headache#	4	03MAR2021	1/2	1	Yes		NA	R (04MAR2021)	N/N
C4591001 1126	15/M/ WHITE	GENRL	Injection site pain/ Left upper arm injection site pain#	3	20MAY2021	1/4	1	Yes		NA/TC	R (23MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
11261279/ Placebo		GENRL	Chills/ Chills#	3	21MAY2021	2/1	2	Yes	NA	R (21MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	11JUN2021	1/3	2	Yes	NA	R (13JUN2021)	N/N
			Pain/ Body aches#	4	11JUN2021	1/3	2	Yes	NA	R (13JUN2021)	N/N
			Pyrexia/ Fever#	4	11JUN2021	1/1	1	Yes	NA	R (11JUN2021)	N/N
C4591001 1126 11261280/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ Left upper arm injection site pain#	3	20MAY2021	1/3	2	Yes	NA/TC	R (22MAY2021)	N/N
		MUSC	Myalgia/ Muscle aches#	3	21MAY2021	2/1	2	Yes	NA/TC	R (21MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	11JUN2021	1/3	2	Yes	NA	R (13JUN2021)	N/N
			Pain/ Body aches#	4	11JUN2021	1/3	2	Yes	NA	R (13JUN2021)	N/N
			Pyrexia/ Fever#	4	11JUN2021	1/1	1	Yes	NA	R (11JUN2021)	N/N
C4591001 1126 11261283/ Placebo	13/F/ ASIAN	GENRL	Fatigue/ Fatigue#	3	18MAY2021	2/2	2	Yes	NA	R (19MAY2021)	N/N
			Injection site pain/ Right Arm Injection Site Pain#	3	18MAY2021	2/2	2	Yes	NA/TC	R (19MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261284/ Placebo	13/F/ ASIAN	NERV	Headache/ Headache#	3	18MAY2021	2/1	2	Yes		NA/TC	R (18MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	10JUN2021	2/1	1	Yes		NA	R (10JUN2021)	N/N
		GENRL	Injection site pain/ Pain, injection site	2	07JAN2021	2/153	2	Yes		NA	R (08JUN2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	18MAY2021	2/3	1	Yes		NA	R (20MAY2021)	N/N
			Injection site pain/ Injection site pain#	3	18MAY2021	2/3	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1126 11261287/ Placebo	15/M/ WHITE		Pyrexia/ Fever, 101F#	3	18MAY2021	2/1	2	Yes		NA/TC	R (18MAY2021)	N/N
		GENRL	Injection site hypoesthesia/ Injection Site numbness#	3	20MAY2021	1/2	1	Yes		NA	R (21MAY2021)	N/N
		GENRL	Injection site pain/ Pain, injection site#	4	11JUN2021	2/1	2	Yes		NA	R (11JUN2021)	N/N
C4591001 1126 11261289/ Placebo	14/F/ WHITE		Injection site swelling/ Swelling, injection site#	4	11JUN2021	2/1	2	Yes		NA	R (11JUN2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	17MAY2021	1/2	2	Yes		NA	R (18MAY2021)	N/N
			Injection site pain/ Pain, Injection Site#	3	17MAY2021	1/3	2	Yes		NA	R (19MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261290/ Placebo	12/M/ NOT REPORTED	SKIN	Pityriasis rosea/ Worsening Pityriasis Rosea	1	23DEC2020	7/28	2	No	O	NA/TC	R (19JAN2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	18MAY2021	1/4	2	Yes		NA/TC	R (21MAY2021)	N/N
		GENRL	Chills/ Chills#	3	19MAY2021	2/3	1	Yes		NA/TC	R (21MAY2021)	N/N
			Injection site pain/ Injection Site Pain#	3	19MAY2021	2/3	1	Yes		NA/TC	R (21MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	09JUN2021	1/2	1	Yes		NA	R (10JUN2021)	N/N
			Injection site pain/ Pain, injection site#	4	09JUN2021	1/4	1	Yes		NA	R (12JUN2021)	N/N
C4591001 1126 11261292/ Placebo	12/F/ ASIAN	GENRL	Chills/ Chills#	3	17MAY2021	1/1	2	Yes		NA/TC	R (17MAY2021)	N/N
			Injection site pain/ Left arm injection site pain#	3	17MAY2021	1/3	2	Yes		NA/TC	R (19MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	18MAY2021	2/2	2	Yes		NA	R (19MAY2021)	N/N
		MUSC	Myalgia/ Muscle aches#	3	18MAY2021	2/2	2	Yes		NA/TC	R (19MAY2021)	N/N
		NERV	Headache/ Headache#	3	18MAY2021	2/2	1	Yes		NA/TC	R (19MAY2021)	N/N
		GENRL	Chills/ Chills#	4	07JUN2021	1/2	2	Yes		NA	R (08JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261294/ Placebo	13/F/ WHITE	GENRL	Pain/ Generalized body aches#	4	07JUN2021	1/2	2	Yes		NA	R (08JUN2021)	N/N
			Pyrexia/ Fever#	4	07JUN2021	1/2	1	Yes		NA	R (08JUN2021)	N/N
			Fatigue/ Fatigue#	4	08JUN2021	2/2	2	Yes		NA	R (09JUN2021)	N/N
			NERV Headache/ Headache#	4	08JUN2021	2/2	1	Yes		NA	R (09JUN2021)	N/N
			GENRL Fatigue/ Fatigue#	3	17JUL2021	2/2	2	Yes		NA	R (18JUL2021)	N/N
			GENRL Injection site pain/ Injection Site Pain#	3	17JUL2021	2/3	1	Yes		NA	R (19JUL2021)	N/N
C4591001 1126 11261296/ Placebo	15/M/ WHITE	INJ&P	Injection site pain/ Injection site pain#	4	07AUG2021	2/2	1	Yes		NA	R (08AUG2021)	N/N
			Accident/ Dirt bike nontraffic accident	2	24JAN2021	17/1	2	No	O	NA/TC/TCN	R (24JAN2021)	N/N
			Contusion/ Left elbow contusion	2	24JAN2021	17/8	1	No	O	NA/TCN	R (31JAN2021)	N/N
			Lip injury/ Lower lip laceration	2	24JAN2021	17/13	1	No	O	NA/TC/TCN	R (05FEB2021)	N/N
			Tooth fracture/ Three teeth fractures	2	24JAN2021	17/1	2	No	O	NA/TC/TCN	R (24JAN2021)	N/N
			GENRL Injection site pain/ Pain injection site#	3	08APR2021	2/2	1	Yes		NA	R (09APR2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261297/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ Injection site pain#	4	27APR2021	2/2	1	Yes		NA	R (28APR2021)	N/N
		GENRL	Injection site pain/ Left Upper Arm Injection Site Pain#	3	19MAY2021	1/3	2	Yes		NA	R (21MAY2021)	N/N
C4591001 1126 11261300/ Placebo	13/M/ ASIAN	GENRL	Injection site pain/ Injection site pain#	4	09JUN2021	1/2	1	Yes		NA	R (10JUN2021)	N/N
		GENRL	Injection site pain/ Left upper arm injection site pain#	3	19MAY2021	1/2	2	Yes		NA/TC	R (20MAY2021)	N/N
C4591001 1126 11261301/ BNT162b2 (30 µg)	15/F/ WHITE	GENRL	Pain/ Generalized body aches#	4	12JUN2021	2/2	1	Yes		NA/TC	R (13JUN2021)	N/N
		GASTR	Nausea/ Nausea	1	24DEC2020	3/2	2	Yes		NA	R (25DEC2020)	N/N
C4591001 1126 11261302/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Left upper arm injection site pain#	3	21MAY2021	1/2	1	Yes		NA	R (22MAY2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	4	11JUN2021	1/3	1	Yes		NA	R (13JUN2021)	N/N
C4591001 1126 11261305/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Left Upper Arm Injection Site Pain#	3	24FEB2021	1/2	2	Yes		NA	R (25FEB2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261306/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ Injection site pain#	4	17MAR2021	1/2	1	Yes		NA	R (18MAR2021)	N/N
		GENRL	Injection site pain/ Left upper arm injection site pain#	3	18MAY2021	1/3	2	Yes		NA	R (20MAY2021)	N/N
C4591001 1126 11261307/ BNT162b2 (30 µg)	14/F/ WHITE	NERV	Migraine/ Migraine headache, worsening	1	24JAN2021	21/C	2	No	O	NA/TC	RG	N/N
C4591001 1126 11261308/ Placebo	12/M/ WHITE	GENRL	Pyrexia/ Fever 101°F#	3	19JUN2021	2/1	2	Yes		NA/TC	R (19JUN2021)	N/N
C4591001 1126 11261309/ BNT162b2 (30 µg)	12/M/ WHITE	GENRL	Injection site pain/ Injection Site Pain#	4	10JUL2021	2/3	1	Yes		NA	R (12JUL2021)	N/N
		GASTR	Lip swelling/ Swollen lips	2	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
C4591001 1126 11261311/ Placebo	13/M/ WHITE		Mouth swelling/ Swollen mouth	2	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	3	02JUN2021	1/2	1	Yes		NA	R (03JUN2021)	N/N
		GENRL	Malaise/ Malaise#	4	22JUN2021	2/2	1	Yes		NA	R (23JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261312/ Placebo	14/F/ WHITE	NERV	Headache/ Headache	1	17JAN2021	13/5	2	No	O	NA	R (21JAN2021)	N/N
		GENRL	Injection site pain/ Left upper arm injection site pain#	3	18MAY2021	1/3	1	Yes		NA	R (20MAY2021)	N/N
		GENRL	Injection site pain/ Pain, injection site#	4	09JUN2021	1/3	2	Yes		NA/TC	R (11JUN2021)	N/N
			Pain/ Generalized body aches#	4	09JUN2021	1/3	2	Yes		NA/TC	R (11JUN2021)	N/N
			Pyrexia/ Fever#	4	09JUN2021	1/3	2	Yes		NA/TC	R (11JUN2021)	N/N
C4591001 1126 11261314/ Placebo	13/M/ WHITE	SKIN	Rash/ Skin rash L side of neck to L scapula	2	01FEB2021	4/3	1	Yes		NA/TC	R (03FEB2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	19MAY2021	1/1	2	Yes		NA	R (19MAY2021)	N/N
			Injection site pain/ Pain, injection site#	3	19MAY2021	1/3	2	Yes		NA	R (21MAY2021)	N/N
		GENRL	Pyrexia/ Fever#	3	20MAY2021	2/1	2	Yes		NA/TC	R (20MAY2021)	N/N
		NERV	Headache/ Headache#	3	20MAY2021	2/1	2	Yes		NA	R (20MAY2021)	N/N
C4591001 1126 11261317/ Placebo	12/F/ WHITE	GENRL	Injection site pain/ Injection Site Pain#	3	17MAY2021	1/3	1	Yes		NA	R (19MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261318/ Placebo	12/F/ WHITE	GENRL	Injection site pain/ Injection site pain#	4	09JUN2021	1/3	1	Yes		NA	R (11JUN2021)	N/N
		GENRL	Malaise/ Malaise#	4	10JUN2021	2/3	1	Yes		NA	R (12JUN2021)	N/N
		GENRL	Chills/ Chills#	3	05AUG2021	1/3	1	Yes		NA	R (07AUG2021)	N/N
C4591001 1126 11261320/ Placebo	12/F/ WHITE		Injection site pain/ Injection site pain#	3	05AUG2021	1/3	1	Yes		NA	R (07AUG2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	18MAY2021	1/2	1	Yes		NA	R (19MAY2021)	N/N
C4591001 1126 11261322/ Placebo	13/M/ ASIAN		Injection site pain/ Pain, injection site#	3	18MAY2021	1/2	1	Yes		NA	R (19MAY2021)	N/N
		GENRL	Injection site pain/ Pain, injection site#	4	09JUN2021	2/1	1	Yes		NA	R (09JUN2021)	N/N
		GENRL	Injection site pain/ Pain, Injection site#	3	25MAY2021	2/4	2	Yes		NA	R (28MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	14JUN2021	1/2	1	Yes		NA	R (15JUN2021)	N/N
C4591001 1126	12/F/ WHITE		Pain/ Generalized body aches#	4	14JUN2021	1/2	1	Yes		NA	R (15JUN2021)	N/N
		NERV	Headache/ Headache#	4	14JUN2021	1/2	1	Yes		NA	R (15JUN2021)	N/N
		GENRL	Chills/ Chills#	3	18MAY2021	1/1	2	Yes		NA	R (18MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
11261325/ Placebo			Injection site pain/ Left upper arm injection site pain#	3	18MAY2021	1/3	1	Yes		NA/TC	R (20MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	19MAY2021	2/1	1	Yes		NA	R (19MAY2021)	N/N
		NERV	Headache/ Headache#	3	19MAY2021	2/1	1	Yes		NA/TC	R (19MAY2021)	N/N
		GENRL	Chills/ Body Chills#	4	09JUN2021	2/1	1	Yes		NA	R (09JUN2021)	N/N
C4591001 1131 11311280/ Placebo	13/F/ WHITE	NERV	Presyncope/ vasovagal reaction secondary to vaccine	1	17DEC2020	1/1	2	Yes		NA	R (17DEC2020)	N/N
C4591001 1131 11311283/ Placebo	15/M/ WHITE	INFEC	Pilonidal cyst/ pilonidal cyst	1	29DEC2020	8/52	2	No	O	NA/TC	R (18FEB2021)	N/N
C4591001 1131 11311285/ Placebo	14/F/ WHITE	GENRL	Injection site pain/ injection site pain#	3	15JUN2021	2/2	1	Yes		NA	R (16JUN2021)	N/N
			Pain/ body aches#	3	15JUN2021	2/2	1	Yes		NA	R (16JUN2021)	N/N
		NERV	Headache/ headache#	3	15JUN2021	2/2	1	Yes		NA	R (16JUN2021)	N/N
C4591001 1131 11311287/ Placebo	12/F/ BLACK OR AFRICAN AMERICAN	RESP	Rhinorrhoea/ rhinorrhea	1	17JAN2021	20/18	1	No	O	NA	R (03FEB2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1131 11311288/ Placebo	12/F/ BLACK OR AFRICAN AMERICAN	BLOOD	Lymphadenopathy/ enlarge lymph nodes- neck(bilateral)	2	27JAN2021	10/8	1	Yes		NA	R (03FEB2021)	N/N
		INFEC	Ear infection/ ear infection#	4	01JUL2021	16/11	1	No	O	NA	R (11JUL2021)	N/N
		GASTR	Vomiting/ vomiting#	4	17JUN2021	2/1	1	No	O	NA	R (17JUN2021)	N/N
		GENRL	Chest pain/ chest pain#	4	17JUN2021	2/2	2	No	O	NA	R (18JUN2021)	N/N
			Pyrexia/ fever#	4	17JUN2021	2/1	1	No	O	NA	R (17JUN2021)	N/N
		INFEC	Pharyngitis streptococcal/ strep throat#	4	17JUN2021	2/3	1	No	O	NA	R (19JUN2021)	N/N
		MUSC	Myalgia/ general myalgia#	4	17JUN2021	2/2	1	No	O	NA	R (18JUN2021)	N/N
		NERV	Headache/ headache#	4	17JUN2021	2/3	1	No	O	NA	R (19JUN2021)	N/N
C4591001 1131 11311293/ Placebo	12/F/ WHITE	RESP	Cough/ cough#	4	17JUN2021	2/1	1	No	O	NA	R (17JUN2021)	N/N
			Nasal congestion/ nasal congestion#	4	17JUN2021	2/4	1	No	O	NA	R (20JUN2021)	N/N
		GASTR	Abdominal pain upper/ Stomach ache#	4	03AUG2021	1/2	2	Yes		NA/TC	R (04AUG2021)	N/N
		GENRL	Pyrexia/ Low grade	4	03AUG2021	1/1	1	Yes		NA/TC	R (03AUG2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1131 11311299/ Placebo	15/M/ WHITE	GENRL	temperature elevation# Injection site pain/ injection site pain#	3	20MAY2021	1/3	1	Yes		NA	R (22MAY2021)	N/N
		GASTR	Nausea/ nausea#	4	11JUN2021	2/1	1	Yes		NA	R (11JUN2021)	N/N
		GENRL	Pyrexia/ febrile#	4	11JUN2021	2/1	2	Yes		NA/TC	R (11JUN2021)	N/N
C4591001 1131 11311300/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ injection site pain#	3	20MAY2021	1/4	2	Yes		NA/TC	R (23MAY2021)	N/N
		INJ&P	Sunburn/ sun burn(face and shoulders)#	3	07JUN2021	19/C	3	No	O	NA/TC	RG	N/N
		GENRL	Chills/ chills#	4	10JUN2021	1/2	2	Yes		NA/TC	R (11JUN2021)	N/N
C4591001 1131 11311301/ BNT162b2 (30 µg)	13/M/ WHITE	MUSC	Pyrexia/ fever# Arthralgia/ sacroiliac joint pain	4	10JUN2021	1/2	2	Yes		NA/TC	R (11JUN2021)	N/N
		MUSC	Arthralgia/ sacroiliac joint pain	1	15JAN2021	5/25	2	No	O	NA	R (08FEB2021)	N/N
		INJ&P	Accident/ skiing accident	2	18FEB2021	14/2	2	No	O	NA/TC/TCN	R (19FEB2021)	N/N
		INJ&P	Clavicle fracture/ right clavicle fracture	2	19FEB2021	15/64	2	No	O	NA/TC/TCN	R (23APR2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1139 11391171/ Placebo	15/M/ WHITE	INJ&P	Skin laceration/ laceration of forehead	2	10MAR2021	65/7	2	No	O	NA	R (16MAR2021)	N/N
C4591001 1139 11391179/ BNT162b2 (30 µg)	15/M/ WHITE	NERV	Syncope/ syncope#	2	12JUL2021	186/1	2	No	O	NA	R (12JUL2021)	N/N
C4591001 1139 11391210/ Placebo	14/M/ WHITE	INJ&P	Concussion/ Concussion#	3	08JUN2021	14/18	3	No	O	NA/TC	R (25JUN2021)	N/N
			Hyphaema/ traumatic hyphema of left eye#	3	08JUN2021	14/18	2	No	O	NA/TC	R (25JUN2021)	N/N
C4591001 1139 11391217/ Placebo	13/M/ WHITE	INFEC	Otitis externa/ Otitis Externa#	4	29JUN2021	22/8	1	No	O	NA/TC	R (06JUL2021)	N/N
C4591001 1139 11391225/ BNT162b2 (30 µg)	12/F/ WHITE	INJ&P	Concussion/ concussion	2	01FEB2021	5/9	2	No	O	NA/TC	R (09FEB2021)	N/N
C4591001 1139 11391246/ Placebo	15/M/ WHITE	MUSC	Arthralgia/ Bilateral knee pain	1	11JAN2021	4/36	2	No	O	NA/TC	R (15FEB2021)	N/N
C4591001 1139 11391248/ Placebo	15/M/ WHITE	INJ&P	Muscle strain/ Abdominal Muscle Strain	2	10MAR2021	41/4	1	No	O	NA	R (13MAR2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
BNT162b2 (30 µg)												
C4591001 1140 11401330/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ pain at injection site#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	4	09JUN2021	2/2	1	Yes		NA	R (10JUN2021)	N/N
			Pyrexia/ fever#	4	09JUN2021	2/2	1	Yes		NA	R (10JUN2021)	N/N
C4591001 1140 11401335/ Placebo	14/F/ WHITE	GENRL	Pyrexia/ fever#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
C4591001 1140 11401338/ Placebo	15/F/ WHITE	GENRL	Injection site pain/ Pain at the injection site#	3	17MAY2021	1/3	1	Yes		NA	RS (19MAY2021)	N/N
		MUSC	Myalgia/ Mayalgias#	3	18MAY2021	2/2	1	Yes		NA	R (19MAY2021)	N/N
		NERV	Headache/ Headache#	3	18MAY2021	2/2	1	Yes		NA	R (19MAY2021)	N/N
		GENRL	Injection site pain/ pain at injection site#	4	07JUN2021	1/C	1	Yes		NA	RG	N/Y
C4591001 1140 11401343/ BNT162b2 (30 µg)	13/F/ AMERICAN INDIAN OR ALASKA NATIVE	NERV	Migraine/ complex migraine	1	23DEC2020	3/1	3	Yes		NA/TC/TCN	R (23DEC2020)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1140 11401353/ Placebo	12/M/ WHITE	MUSC	Neck pain/ neck pain	2	03FEB2021	23/3	2	No	O	NA/TC	R (05FEB2021)	N/N
		GENRL	Injection site pain/ Pain at the injection site#	3	21MAY2021	1/3	1	Yes		NA	R (23MAY2021)	N/N
		GENRL	Pyrexia/ Fever#	3	22MAY2021	2/2	1	Yes		NA	R (23MAY2021)	N/N
C4591001 1140 11401354/ BNT162b2 (30 µg)	15/F/ WHITE	CONG	Syringomyelia/ Thoracic spinal syrinx#	2	JUN2021	140/C	3	No	O	NA/TC/TCN	N	Y/N
C4591001 1140 11401356/ Placebo	14/F/ MULTIPLE	GENRL	Fatigue/ Fatigue#	3	20MAY2021	1/2	1	Yes		NA	R (21MAY2021)	N/N
			Injection site pain/ Pain at injection site#	3	20MAY2021	1/2	1	Yes		NA	R (21MAY2021)	N/N
			Pyrexia/ Fever#	3	20MAY2021	1/3	1	Yes		NA	R (22MAY2021)	N/N
		NERV	Headache/ Headache#	3	20MAY2021	1/2	1	Yes		NA	R (21MAY2021)	N/N
C4591001 1140 11401357/ Placebo	15/F/ WHITE	GENRL	Chills/ Mild Chills	2	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/Y
			Fatigue/ Mild Fatigue	2	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/Y

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Injection site pain/ mild injection site pain	2	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/Y
C4591001 1140 11401362/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ pain at injection site#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
C4591001 1140 11401364/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	22MAY2021	2/3	1	Yes		NA	R (24MAY2021)	N/N
C4591001 1140 11401365/ BNT162b2 (30 µg)	15/M/ WHITE	PSYCH	Suicidal ideation/ Suicidal Ideation	2	04APR2021	76/2	3	No	O	NA/TC/TCN	R (05APR2021)	Y/N
C4591001 1140 11401366/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	22MAY2021	2/3	1	Yes		NA	R (24MAY2021)	N/N
C4591001 1140 11401372/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ pain at injection site#	3	18MAY2021	1/C	1	Yes		NA	RG	N/Y
C4591001 1140 11401374/ Placebo	14/F/ WHITE	GENRL	Pain/ body aches#	3	28MAY2021	1/3	1	Yes		NA/TC	R (30MAY2021)	N/N
		GASTR	Vomiting/ vomiting#	3	30MAY2021	3/1	1	Yes		NA	R (30MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1140 11401383/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	21MAY2021	1/3	1	Yes		NA	R (23MAY2021)	N/N
C4591001 1140 11401384/ Placebo	14/F/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	18MAY2021	2/3	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1140 11401385/ BNT162b2 (30 µg)	12/F/ WHITE	IMMUN	Seasonal allergy/ Seasonal Allergies	2	MAR2021	34/C	2	No	O	NA	RG	N/N
C4591001 1140 11401387/ Placebo	12/M/ WHITE	INJ&P	Contusion/ Left arm contusion#	2	16MAY2021	109/8	1	No	O	NA/TCN	R (23MAY2021)	N/N
C4591001 1140 11401388/ Placebo	15/M/ WHITE	GENRL	Fatigue/ fatigue#	3	19MAY2021	1/2	1	Yes		NA	R (20MAY2021)	N/N
			Injection site pain/ pain at injection site#	3	19MAY2021	1/3	1	Yes		NA	R (21MAY2021)	N/N
		NERV	Headache/ headache#	3	20MAY2021	2/1	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1140 11401389/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ pain at injection site#	3	19MAY2021	1/3	1	Yes		NA	R (21MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1140 11401392/ Placebo	15/M/ WHITE	GENRL	Fatigue/ Fatigue#	3	19MAY2021	1/2	1	Yes		NA	R (20MAY2021)	N/N
			Injection site pain/ Pain at injection site#	3	19MAY2021	1/1	1	Yes		NA	R (19MAY2021)	N/N
C4591001 1140 11401395/ Placebo	12/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	20MAY2021	1/1	1	Yes		NA	R (20MAY2021)	N/N
		NERV	Headache/ Headache#	3	20MAY2021	1/1	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1142 11421326/ Placebo	12/F/ WHITE	GENRL	Injection site erythema/ injection site redness#	3	25MAY2021	2/6	1	Yes		NA	R (30MAY2021)	N/N
			Injection site pain/ injection site pain#	3	25MAY2021	2/6	1	Yes		NA	R (30MAY2021)	N/N
			Injection site swelling/ injection site swelling#	3	25MAY2021	2/6	1	Yes		NA	R (30MAY2021)	N/N
C4591001 1142 11421335/ Placebo	13/F/ WHITE	GENRL	Fatigue/ fatigue#	3	30JUL2021	1/2	2	Yes		NA	R (31JUL2021)	N/N
			Injection site pain/ injection site pain#	3	30JUL2021	1/2	2	Yes		NA	R (31JUL2021)	N/N
			Malaise/ malaise#	3	30JUL2021	1/2	2	Yes		NA	R (31JUL2021)	N/N

16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age													
Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
C4591001 1142 11421352/ Placebo	13/M/ WHITE	INJ&P	Patella fracture/ Fracture of left patella	2	31JAN2021	28/C	3	No	O	NA	RG	N/N	
C4591001 1142 11421355/ Placebo	12/M/ MULTIPLE	GENRL	Injection site pain/ injection site pain#	3	27JUL2021	1/2	2	Yes		NA	R (28JUL2021)	N/N	
C4591001 1142 11421356/ Placebo	14/F/ BLACK OR AFRICAN AMERICAN	GENRL	Injection site pain/ injection site pain#	3	27JUL2021	1/2	2	Yes		NA	R (28JUL2021)	N/N	
C4591001 1142 11421385/ BNT162b2 (30 µg)	15/M/ NOT REPORTED	BLOOD	Lymphadenopathy/ left supraclavicular lymph node swelling	1	07JAN2021	8/8	1	Yes		NA	R (14JAN2021)	N/N	
C4591001 1142 11421393/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ injection site pain#	3	31AUG2021	1/3	1	Yes		NA	R (02SEP2021)	N/N	
C4591001 1142 11421394/ BNT162b2 (30 µg)	14/M/ NOT REPORTED	NERV	Paraesthesia/ transient feeling of pins and needles to torso	1	18JAN2021	8/C	1	No	O	NA	RG	N/N	
C4591001 1147 11471262/ BNT162b2 (30 µg)	14/F/ WHITE	PSYCH	Generalised anxiety disorder/ Generalized anxiety disorder (worsening)	2	25JAN2021	22/C	1	No	O	NA/TC	N	N/N	

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1147 11471263/ BNT162b2 (30 µg)	12/M/ WHITE	NEOPL	Hair follicle tumour benign/ Pilomatrixoma	1	2020	1/	1	No	O	NA/TC/TCN	R (09FEB2021)	N/N
C4591001 1147 11471270/ Placebo	15/F/ WHITE	INV	Body temperature increased/ Increased body temperature#	3	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		MUSC	Myalgia/ Myalgia#	3	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		NERV	Headache/ Headache#	3	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
C4591001 1147 11471281/ Placebo	13/M/ WHITE	INFEC	Appendicitis/ Acute appendicitis	2	22JAN2021	19/2	4	No	O	NA/TC/TCN	R (23JAN2021)	Y/N
			Focal peritonitis/ localized peritonitis, without perforation or gangrene	2	22JAN2021	19/2	4	No	O	NA/TC/TCN	R (23JAN2021)	Y/N
C4591001 1147 11471292/ Placebo	14/M/ ASIAN	SKIN	Acne/ Acne vulgaris (new diagnosis)	2	25JAN2021	17/C	1	No	O	NA/TC	N	N/N
C4591001 1147 11471302/ BNT162b2 (30 µg)	15/F/ WHITE	RESP	Nasal congestion/ Nasal congestion	2	19MAR2021	70/3	1	No	O	NA/TC	R (21MAR2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1147 11471307/ Placebo	13/M/ WHITE	GENRL	Rhinorrhoea/ Runny nose	2	19MAR2021	70/3	1	No	O	NA/TC	R (21MAR2021)	N/N
			Sneezing/ Sneezing	2	19MAR2021	70/3	1	No	O	NA/TC	R (21MAR2021)	N/N
			Injection site erythema/ Redness at injection site#	3	13MAY2021	1/4	1	Yes		NA	R (16MAY2021)	N/N
			Injection site pain/ Pain at injection site#	3	13MAY2021	1/4	1	Yes		NA	R (16MAY2021)	N/N
			NERV Headache/ Headache#	3	13MAY2021	1/4	1	Yes		NA	R (16MAY2021)	N/N
C4591001 1147 11471310/ BNT162b2 (30 µg)	15/F/ WHITE	RESP	Nasal congestion/ Nasal congestion	1	02JAN2021	13/8	1	No	O	NA/TC	R (09JAN2021)	N/N
C4591001 1147 11471320/ BNT162b2 (30 µg)	15/F/ WHITE	EAR	Ear pain/ Left ear pain	2	JAN2021	1/C	1	No	O	NA/TC	RG	N/N
		PSYCH	Anxiety/ Anxiety#	2	MAY2021	95/C	2	No	O	NA/TC	N	N/N
C4591001 1147 11471321/ Placebo	15/M/ BLACK OR AFRICAN AMERICAN	METAB	Glucose tolerance impaired/ pre-diabetes#	4	02JUL2021	26/C	1	No	O	NA	N	N/N
			Vitamin D deficiency/	4	02JUL2021	26/C	1	No	O	NA/TC	N	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1147 11471322/ Placebo	12/M/ WHITE	EAR	vitamin D deficiency# Ear pain/ Right ear pain	1	25JAN2021	21/7	1	No	O	NA/TC	R (31JAN2021)	N/N
		INFEC	Conjunctivitis/ Acute conjunctivitis, left	2	25FEB2021	30/C	1	No	O	NA/TC	RG	N/N
C4591001 1147 11471323/ Placebo	14/M/ WHITE	SKIN	Dermatitis contact/ Allergic reaction to surgical dressings.	2	09FEB2021	14/C	2	No	O	NA/TC	RG	N/N
C4591001 1147 11471327/ BNT162b2 (30 µg)	14/M/ WHITE	GENRL	Pyrexia/ Fever (104.7)	1	06JAN2021	2/3	4	Yes		P/TC	R (08JAN2021)	N/N
C4591001 1147 11471331/ BNT162b2 (30 µg)	13/F/ WHITE	INJ&P	Hand fracture/ Fracture of middle phalanx of left index finger	2	24FEB2021	28/C	1	No	O	NA	RG	N/N
C4591001 1147 11471336/ Placebo	15/F/ WHITE	GASTR	Nausea/ Nausea	2	11APR2021	75/C	1	No	O	NA	N	N/N
C4591001 1147 11471345/ Placebo	15/M/ WHITE	MUSC	Myalgia/ Generalized muscle pain#	3	20MAY2021	2/2	1	Yes		NA	R (21MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1150 11501120/ Placebo	15/M/ WHITE	MUSC	Tendonitis/ Tendonitis	2	MAR2021	116/	1	No	O	NA	R	N/N
		GENRL	Injection site pain/ Pain at injection site#	3	21MAY2021	2/1	1	Yes		NA	R (21MAY2021)	N/N
C4591001 1150 11501121/ Placebo	15/F/ WHITE	GENRL	Pyrexia/ Fever#	4	10JUN2021	1/2	1	Yes		NA	R (11JUN2021)	N/N
		MUSC	Myalgia/ Muscle Pain#	4	10JUN2021	1/2	1	Yes		NA	R (11JUN2021)	N/N
C4591001 1150 11501125/ Placebo	14/M/ BLACK OR AFRICAN AMERICAN	GENRL	Injection site pain/ Injection Site pain#	3	18MAY2021	1/2	1	Yes		NA	R (19MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	10JUN2021	1/2	1	Yes		NA	R (11JUN2021)	N/N
C4591001 1150 11501127/ BNT162b2 (30 µg)	15/M/ WHITE	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
C4591001 1150 11501129/ Placebo	12/F/ WHITE	INJ&P	Concussion/ Concussion	2	11JAN2021	63/60	2	No	O	NA	R (11MAR2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	14MAY2021	2/3	2	Yes		NA	R (16MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1150 11501130/ BNT162b2 (30 µg)	12/F/ WHITE	GASTR	Injection site pain/ Pain at injection site#	3	14MAY2021	2/3	2	Yes		NA	R (16MAY2021)	N/N
			Pain/ Body Aches#	3	14MAY2021	2/3	2	Yes		NA	R (16MAY2021)	N/N
			Pyrexia/ Fever#	3	14MAY2021	2/1	1	Yes		NA	R (14MAY2021)	N/N
C4591001 1150 11501131/ Placebo	15/M/ WHITE	GASTR	Nausea/ Nausea	2	09NOV2020	1/3	2	Yes		NA	R (11NOV2020)	N/N
		NERV	Dizziness/ Dizziness	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N
C4591001 1150 11501131/ Placebo	15/M/ WHITE	GENRL	Fatigue/ Fatigue#	3	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
			Injection site pain/ Pain at injection site#	3	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
			Pain/ Generalized Body Aches#	3	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
		NERV	Headache/ Headache#	3	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	15MAR2021	1/2	2	Yes		NA	R (16MAR2021)	N/N
			Injection site pain/ Pain at injection site#	4	15MAR2021	1/2	2	Yes		NA	R (16MAR2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Pain/ Generalized Body Aches#	4	15MAR2021	1/2	2	Yes		NA	R (16MAR2021)	N/N
		NERV	Headache/ Headache#	4	15MAR2021	1/2	2	Yes		NA	R (16MAR2021)	N/N
		PSYCH	Major depression/ Current severe episode of major depressive disorder without psychotic features without prior episode#	4	MAR2021	1/	3	No	O	NA/TC	R (10AUG2021)	Y/N
C4591001 1150 11501132/ BNT162b2 (30 µg)	14/M/ WHITE	GASTR	Diarrhoea/ Diarrhea	2	09NOV2020	1/2	2	Yes		NA	R (10NOV2020)	N/N
C4591001 1150 11501134/ Placebo	15/M/ WHITE	GENRL	Chills/ Chills#	3	18MAY2021	2/2	1	Yes		NA	R (19MAY2021)	N/N
C4591001 1150 11501166/ Placebo	14/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	21MAY2021	2/2	1	Yes		NA	R (22MAY2021)	N/N
		MUSC	Myalgia/ Muscle Pain#	4	09JUN2021	2/2	2	Yes		NA	R (10JUN2021)	N/N
C4591001 1150 11501168/ BNT162b2 (30 µg)	13/M/ WHITE	PSYCH	Depression/ Depression	2	MAR2021	69/C	2	No	O	NA	RG	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1150 11501176/ Placebo	14/F/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	18MAY2021	1/3	2	Yes		NA	R (20MAY2021)	N/N
		GENRL	Chills/ Chills#	3	19MAY2021	2/1	1	Yes		NA	R (19MAY2021)	N/N
			Fatigue/ Fatigue#	3	19MAY2021	2/1	2	Yes		NA	R (19MAY2021)	N/N
		NERV	Syncope/ Fainting#	3	19MAY2021	2/1	2	Yes		NA	R (19MAY2021)	N/N
C4591001 1150 11501182/ Placebo	15/F/ WHITE	GENRL	Injection site pain/ Injection Site Pain#	3	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/N
C4591001 1150 11501185/ Placebo	14/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	13MAY2021	1/2	1	Yes		NA	R (14MAY2021)	N/N
			Injection site bruising/ Bruise at injection site#	3	13MAY2021	1/5	1	Yes		NA	R (17MAY2021)	N/N
			Injection site pain/ Pain at injection site#	3	13MAY2021	1/2	1	Yes		NA	R (14MAY2021)	N/N
C4591001 1150 11501189/ Placebo	15/F/ WHITE	GASTR	Nausea/ Nausea#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1150 11501190/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	17MAY2021	1/2	2	Yes		NA	R (18MAY2021)	N/N
			Injection site pain/ Pain at injection site#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	18MAY2021	2/1	1	Yes		NA	R (18MAY2021)	N/N
C4591001 1150 11501193/ Placebo	14/F/ WHITE	PSYCH	Attention deficit hyperactivity disorder/ ADHD	1	DEC2020	1/C	1	No	O	NA	RG	N/N
C4591001 1150 11501204/ Placebo	14/M/ WHITE	GENRL	Fatigue/ Fatigue#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
C4591001 1150 11501207/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	18MAY2021	1/2	1	Yes		NA	R (19MAY2021)	N/N
C4591001 1150 11501210/ Placebo	12/F/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	24MAY2021	1/3	2	Yes		NA	R (26MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	14JUN2021	1/3	2	Yes		NA	R (16JUN2021)	N/N
			Injection site pain/ Pain at injection site#	4	14JUN2021	1/3	2	Yes		NA	R (16JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		MUSC	Arthralgia/ Generalized joint Pain#+	4	14JUN2021	1/3	1	Yes		NA	R (16JUN2021)	N/N
			Myalgia/ Muscle Pain#	4	14JUN2021	1/3	1	Yes		NA	R (16JUN2021)	N/N
		GENRL	Pyrexia/ Fever#	4	15JUN2021	2/1	1	Yes		NA	R (15JUN2021)	N/N
C4591001 1150 11501212/ Placebo	12/F/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	13MAY2021	1/2	1	Yes		NA	R (14MAY2021)	N/N
C4591001 1150 11501214/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ Injection Site pain#	3	19MAY2021	2/3	1	Yes		NA	R (21MAY2021)	N/N
		NERV	Headache/ Headache#	4	11JUN2021	2/2	1	Yes		NA	R (12JUN2021)	N/N
C4591001 1150 11501215/ Placebo	14/F/ WHITE	GENRL	Injection site pain/ Injection Site pain#	3	19MAY2021	2/2	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1150 11501218/ Placebo	15/F/ WHITE	GENRL	Injection site pain/ Injection site pain#	3	18MAY2021	2/2	2	Yes		NA	RS (19MAY2021)	N/N
		NERV	Headache/ Headache#	4	09JUN2021	2/1	1	Yes		NA	R (09JUN2021)	N/N
C4591001 1150 11501222/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Pain at injection site#	4	01JUN2021	1/3	1	Yes		NA	R (03JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1150 11501224/ Placebo	12/M/ WHITE	GENRL	Fatigue/ Fatigue#	4	02JUN2021	2/2	1	Yes		NA	R (03JUN2021)	N/N
		NERV	Headache/ Headache#	4	02JUN2021	2/2	1	Yes		NA	R (03JUN2021)	N/N
		GENRL	Injection site pain/ Pain at injection site#	3	18MAY2021	1/3	1	Yes		NA	R (20MAY2021)	N/N
		GENRL	Chills/ Chills#	4	07JUN2021	1/2	1	Yes		NA	R (08JUN2021)	N/N
C4591001 1150 11501229/ Placebo	14/F/ WHITE		Fatigue/ Fatigue#	4	07JUN2021	1/2	1	Yes		NA	R (08JUN2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	14MAY2021	1/2	2	Yes		NA	R (15MAY2021)	N/N
			Injection site pain/ Pain at injection site#	3	14MAY2021	1/3	2	Yes		NA	R (16MAY2021)	N/N
			Pyrexia/ Fever#	3	14MAY2021	1/2	1	Yes		NA	R (15MAY2021)	N/N
		GENRL	Chills/ Chills#	4	02JUN2021	1/2	2	Yes		NA	R (03JUN2021)	N/N
			Fatigue/ Fatigue#	4	02JUN2021	1/3	2	Yes		NA	R (04JUN2021)	N/N
			Injection site erythema/ Redness at injection site#	4	02JUN2021	1/3	2	Yes		NA	R (04JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Injection site pain/ Pain at injection site#	4	02JUN2021	1/3	2	Yes		NA	R (04JUN2021)	N/N
			Pyrexia/ Fever#	4	02JUN2021	1/2	2	Yes		NA	R (03JUN2021)	N/N
		NERV	Headache/ Headache#	4	02JUN2021	1/3	2	Yes		NA	R (04JUN2021)	N/N
		INFEC	Hand-foot-and- mouth disease/ Hand, foot and mouth disease#	4	10JUN2021	9/8	2	No	O	NA	R (17JUN2021)	N/N
C4591001 1150 11501231/ Placebo	14/F/ ASIAN	GENRL	Fatigue/ Fatigue#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
			Injection site pain/ Pain at injection site#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
			Pain/ Body Aches#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
			Pyrexia/ Fever#	3	17MAY2021	1/1	1	Yes		NA	R (17MAY2021)	N/N
C4591001 1150 11501232/ Placebo	14/M/ WHITE	GENRL	Chills/ Chills#	3	19MAY2021	2/1	1	Yes		NA	R (19MAY2021)	N/N
		GENRL	Pyrexia/ Fever (101.0)#	4	08JUN2021	2/1	1	Yes		NA	R (08JUN2021)	N/N
C4591001 1150	15/M/ WHITE	GENRL	Injection site pain/ Injection Site Pain#	4	08JUN2021	2/2	2	Yes		NA	R (09JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
11501235/ Placebo C4591001 1150 11501242/ Placebo	15/M/ WHITE	GENRL	Fatigue/ Fatigue#	3	11MAR2021	2/2	1	Yes		NA	R (12MAR2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	06APR2021	2/2	1	Yes		NA	R (07APR2021)	N/N
			Injection site pain/ Injection Site Pain#	4	06APR2021	2/2	1	Yes		NA	R (07APR2021)	N/N
		INJ&P	Traumatic renal injury/ Laceration of Left Kidney#	4	17JUL2021	104/C	2	No	O	NA	RG	Y/N
C4591001 1150 11501243/ Placebo	12/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	15MAY2021	2/2	1	Yes		NA	R (16MAY2021)	N/N
			Injection site pain/ Injection Site Pain#	3	15MAY2021	2/2	1	Yes		NA	R (16MAY2021)	N/N
		GENRL	Injection site pain/ Injection Site Pain#	4	04JUN2021	2/2	1	Yes		NA	R (05JUN2021)	N/N
C4591001 1150 11501248/ Placebo	13/M/ WHITE	INJ&P	Tibia fracture/ Broken Left Tibia	2	07APR2021	79/C	2	No	O	NA	RG	N/N
		GENRL	Injection site pain/ Pain at injection site#	3	19MAY2021	1/3	1	Yes		NA	R (21MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	20MAY2021	2/2	1	Yes		NA	R (21MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1150 11501249/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Injection Site Pain#	4	05JUN2021	2/2	2	Yes		NA	R (06JUN2021)	N/N
			Pyrexia/ Fever (100.7)#	4	05JUN2021	2/2	1	Yes		NA	R (06JUN2021)	N/N
C4591001 1150 11501250/ BNT162b2 (30 µg)	13/F/ NOT REPORTED	PSYCH	Suicidal ideation/ Suicidal Ideation	2	03MAR2021	44/5	2	No	O	NA/TC/TCN	R (07MAR2021)	Y/N
C4591001 1150 11501257/ Placebo	15/F/ WHITE	GENRL	Injection site pain/ Injection site pain#	3	15MAY2021	2/2	1	Yes		NA	R (16MAY2021)	N/N
C4591001 1150 11501261/ Placebo	13/M/ WHITE	GENRL	Fatigue/ Fatigue#	4	04JUN2021	2/1	2	Yes		NA	R (04JUN2021)	N/N
		NERV	Headache/ Headache#	4	04JUN2021	2/1	1	Yes		NA	R (04JUN2021)	N/N
C4591001 1150 11501263/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ Injection Site Pain#	3	20MAY2021	2/2	1	Yes		NA	R (21MAY2021)	N/N
		NERV	Headache/ Headache#	3	20MAY2021	2/2	1	Yes		NA	R (21MAY2021)	N/N
		GENRL	Injection site pain/ Injection Site Pain#	4	12JUN2021	2/2	2	Yes		NA	R (13JUN2021)	N/N
C4591001 1150	12/M/ WHITE	GENRL	Chills/ Chills#	3	15MAY2021	2/2	1	Yes		NA	R (16MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
11501271/ Placebo			Fatigue/ Fatigue#	3	15MAY2021	2/2	1	Yes		NA	R (16MAY2021)	N/N
		MUSC	Myalgia/ Muscle Pain#	4	03JUN2021	2/2	1	Yes		NA	R (04JUN2021)	N/N
C4591001 1150 11501272/ Placebo	14/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	15MAY2021	2/1	1	Yes		NA	R (15MAY2021)	N/N
C4591001 1150 11501280/ Placebo	14/F/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	19MAY2021	1/2	1	Yes		NA	R (20MAY2021)	N/N
		NERV	Headache/ Headache#	3	20MAY2021	2/1	2	Yes		NA	R (20MAY2021)	N/N
		MUSC	Myalgia/ Muscle Aches#	4	11JUN2021	2/1	1	Yes		NA	R (11JUN2021)	N/N
C4591001 1150 11501282/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	17MAY2021	1/3	1	Yes		NA	R (19MAY2021)	N/N
		INFEC	Tinea infection/ Ringworm#	3	07JUN2021	22/C	1	No	O	NA	RG	N/N
C4591001 1150 11501284/ Placebo	14/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	17MAY2021	1/3	2	Yes		NA	R (19MAY2021)	N/N
			Injection site pain/ Pain at injection site#	3	17MAY2021	1/3	2	Yes		NA	R (19MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1150 11501287/ BNT162b2 (30 µg)	12/M/ WHITE		Pain/ Body Aches#	3	17MAY2021	1/2	2	Yes		NA	R (18MAY2021)	N/N
			Pyrexia/ Fever#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
		NERV	Headache/ Headache#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
		GENRL	Pyrexia/ Fever (100.7)#	4	07JUN2021	1/4	1	Yes		NA	R (10JUN2021)	N/N
		MUSC	Myalgia/ Muscle Aches#	4	07JUN2021	1/4	2	Yes		NA	R (10JUN2021)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	08JAN2021	2/1	1	Yes		NA/TC	R (08JAN2021)	N/N
C4591001 1150 11501291/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	19MAY2021	1/4	2	Yes		NA	R (22MAY2021)	N/Y
		GENRL	Fatigue/ Fatigue#	3	20MAY2021	2/3	2	Yes		NA	R (22MAY2021)	N/N
		NERV	Headache/ Headache#	3	20MAY2021	2/2	2	Yes		NA	R (21MAY2021)	N/N
C4591001 1150 11501294/ Placebo	12/F/ BLACK OR AFRICAN AMERICAN	EAR	Conductive deafness/ Left sided mild conductive hearing loss	1	14JAN2021	4/	2	Yes		NA	R	N/N
		GENRL	Injection site pain/ Pain at injection site#	3	27MAY2021	1/3	1	Yes		NA	R (29MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
C4591001 1150 11501298/ Placebo	13/M/ ASIAN	GENRL	Injection site swelling/ Swollen at injection site#	3	27MAY2021	1/3	1	Yes		NA	R (29MAY2021)	N/N	
			Injection site pain/ Pain at injection site#	4	16JUN2021	1/2	1	Yes		NA	R (17JUN2021)	N/N	
		GENRL	Chills/ Chills#	3	14MAY2021	2/1	1	Yes		NA	R (14MAY2021)	N/N	
			Pyrexia/ Fever#	3	14MAY2021	2/1	1	Yes		NA	R (14MAY2021)	N/N	
			NERV	Headache/ Headache#	3	14MAY2021	2/1	1	Yes		NA	R (14MAY2021)	N/N
			GENRL	Chills/ Chills#	4	01JUN2021	1/1	1	Yes		NA	R (01JUN2021)	N/N
C4591001 1152 11521615/ Placebo	15/M/ WHITE	SKIN	Pyrexia/ Fever#	4	01JUN2021	1/1	1	Yes		NA	R (01JUN2021)	N/N	
			Rash/ generalized rash upper body	1	03DEC2020	1/8	1	No	O	NA	R (10DEC2020)	N/N	
C4591001 1152 11521617/ BNT162b2 (30 µg)	13/M/ WHITE	INJ&P	Upper limb fracture/ Elbow Fracture#	2	01AUG2021	217/C	2	No	O	NA/TC/TCN	N	Y/N	
C4591001 1152 11521640/	15/M/ WHITE	INFEC	Ear infection/ right ear infection, NFI	1	20DEC2020	14/7	2	No	O	NA/TC	R (26DEC2020)	N/N	

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
BNT162b2 (30 µg) C4591001 1152 11521641/ BNT162b2 (30 µg)	12/M/ WHITE	EYE	Eyelid rash/ rash right eyelid	1	07DEC2020	1/2	1	Yes		NA	R (08DEC2020)	N/N
		SKIN	Rash/ rash bilateral extremities	1	08DEC2020	2/1	1	Yes		NA	R (08DEC2020)	N/N
C4591001 1152 11521654/ Placebo	14/F/ WHITE	PSYCH	Depression/ Worsened Depression	1	26DEC2020	18/C	2	No	O	NA/TC	N	N/N
C4591001 1152 11521664/ Placebo	13/F/ WHITE	INJ&P	Ankle fracture/ FRACTURED LEFT ANKLE	2	18JUN2021	171/C	2	No	O	NA/TC/TCN	N	N/N
			Fall/ FALL	2	18JUN2021	171/1	2	No	O	NA	R (18JUN2021)	N/N
C4591001 1152 11521669/ Placebo	15/F/ ASIAN	NERV	Headache/ headache	2	30MAR2021	91/1	1	No	O	NA	R (30MAR2021)	N/N
C4591001 1152 11521683/ BNT162b2 (30 µg)	14/F/ WHITE	BLOOD	Lymphadenopathy/ Swollen Lymph Node (Left Clavicle)	1	26DEC2020	12/C	1	No	O	NA	N	N/N
C4591001 1152	15/F/ WHITE	RESP	Nasal congestion/ Nasal Congestion	2	03MAY2021	118/C	2	No	O	NA/TC	N	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
11521687/ Placebo C4591001 1152 11521688/ Placebo	12/F/ WHITE	RESP	Nasal congestion/ Nasal Congestion	2	01MAY2021	116/C	2	No	O	NA/TC	N	N/N
		GENRL	Chills/ Chills#	4	15JUN2021	2/2	2	Yes		NA/TC	R (16JUN2021)	N/N
			Fatigue/ fatigue#	4	15JUN2021	2/C	2	Yes		NA/TC	RG	N/N
		NERV	Headache/ headache#	4	15JUN2021	2/C	2	Yes		NA/TC	RG	N/N
C4591001 1152 11521690/ Placebo	14/F/ WHITE	INFEC	Ear infection/ Left ear infection#	3	11JUN2021	15/C	2	No	O	NA/TC/TCN	N	N/N
C4591001 1152 11521696/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ site injection arm pain#	3	25MAY2021	2/2	2	Yes		NA/TC	R (26MAY2021)	N/N
		MUSC	Myalgia/ Myalgias#	3	25MAY2021	2/2	2	Yes		NA/TC	R (26MAY2021)	N/N
C4591001 1152 11521697/ BNT162b2 (30 µg)	12/F/ ASIAN	GENRL	Injection site pain/ Injection Site Pain	1	18DEC2020	1/4	2	Yes		NA/TC	R (21DEC2020)	N/N
		GENRL	Chills/ Chills	1	19DEC2020	2/1	2	Yes		NA	R (19DEC2020)	N/N
			Fatigue/ Fatigue	1	19DEC2020	2/1	2	Yes		NA	R (19DEC2020)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Injection site swelling/ Injection Site Swelling	1	19DEC2020	2/2	2	Yes		NA	R (20DEC2020)	N/N
			Pyrexia/ Fever	1	19DEC2020	2/1	1	Yes		NA/TC	R (19DEC2020)	N/N
C4591001 1152 11521704/ BNT162b2 (30 µg)	14/M/ WHITE	BLOOD	Lymphadenopathy/ swollen lymph node left axilla	1	26DEC2020	6/10	2	Yes		NA	R (04JAN2021)	N/N
C4591001 1152 11521706/ Placebo	13/M/ WHITE	GENRL	Fatigue/ Fatigue	1	21DEC2020	1/7	3	Yes		NA/TC	R (27DEC2020)	N/N
		NERV	Headache/ HEADACHE	1	26DEC2020	6/2	3	Yes		NA/TC	R (27DEC2020)	N/N
C4591001 1152 11521739/ Placebo	12/M/ WHITE	MUSC	Musculoskeletal stiffness/ Left arm stiffness#	3	22MAY2021	2/7	1	Yes		NA	R (28MAY2021)	N/N
C4591001 1152 11521740/ Placebo	15/F/ WHITE	INJ&P	Tooth fracture/ Chipped baby tooth	2	17FEB2021	22/1	1	No	O	NA	R (17FEB2021)	N/N
		GENRL	Fatigue/ fatigue#	3	25MAY2021	2/2	2	Yes		NA/TC	R (26MAY2021)	N/N
			Injection site pain/ site injection arm pain#	3	25MAY2021	2/C	2	Yes		NA/TC	RG	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1152 11521749/ BNT162b2 (30 µg)	13/F/ ASIAN	GASTR	Abdominal pain/ ABDOMINAL CRAMPS	1	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
C4591001 1152 11521752/ Placebo	15/M/ ASIAN	INJ&P	Joint injury/ left wrist joint injured#	3	26MAY2021	2/C	1	No	O	NA/TCN	RG	N/N
C4591001 1152 11521756/ BNT162b2 (30 µg)	12/F/ WHITE	GASTR	Diarrhoea/ Diarrhea	2	06FEB2021	6/3	1	No	O	NA	R (08FEB2021)	N/N
C4591001 1156 11561310/ BNT162b2 (30 µg)	12/F/ BLACK OR AFRICAN AMERICAN	INFEC	Body tinea/ TINEA CORPORIS	1	08DEC2020	8/18	1	No	O	NA	R (25DEC2020)	N/N
C4591001 1156 11561357/ Placebo	12/F/ WHITE	INFEC	Appendicitis/ APPENDICITIS#	4	10JUN2021	4/1	2	Yes		NA/TC	R (10JUN2021)	Y/N
C4591001 1223 12231267/ BNT162b2 (30 µg)	12/M/ WHITE	GENRL	Fatigue/ fatigue	2	27JAN2021	1/3	2	Yes		NA	R (29JAN2021)	N/N
			Pyrexia/ fever	1	27JAN2021	21/3	1	Yes		NA/TC	R (29JAN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		MUSC	Myalgia/ generalized muscle aches	2	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
C4591001 1223 12231269/ Placebo	15/F/ WHITE	GENRL	Fatigue/ fatigue#	3	21MAY2021	2/2	1	Yes		NA/TCN	R (22MAY2021)	N/N
C4591001 1223 12231271/ BNT162b2 (30 µg)	12/M/ WHITE	GENRL	Injection site pain/ injection site pain	1	29JAN2021	22/4	1	Yes		NA	R (01FEB2021)	N/N
C4591001 1223 12231273/ Placebo	15/M/ WHITE	CARD	Myocarditis/ Myopericarditis#	4	12JUN2021	3/2	3	No	O	NA/TC	R (13JUN2021)	Y/N
C4591001 1223 12231277/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ injection site pain#	3	26MAY2021	2/2	1	Yes		NA	R (27MAY2021)	N/N
		GENRL	Pyrexia/ fever#	4	14JUN2021	1/3	1	Yes		NA/TC	R (16JUN2021)	N/N
		NERV	Headache/ headache#	4	14JUN2021	1/3	1	Yes		NA	R (16JUN2021)	N/N
C4591001 1223 12231279/ Placebo	13/F/ WHITE	GENRL	Fatigue/ fatigue#	4	11JUN2021	1/3	1	Yes		NA	R (13JUN2021)	N/N
		MUSC	Pain in extremity/ sore arm#	4	11JUN2021	1/3	1	Yes		NA/TC	R (13JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1223 12231281/ BNT162b2 (30 µg)	14/F/ WHITE	GENRL	Pyrexia/ fever	2	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
		MUSC	Myalgia/ muscle ache generalized	2	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
		NERV	Headache/ headache	2	03FEB2021	2/3	1	Yes		NA/TC	R (05FEB2021)	N/N
C4591001 1223 12231283/ Placebo	14/M/ WHITE	GENRL	Fatigue/ fatigue#	3	20MAY2021	1/2	1	Yes		NA	R (21MAY2021)	N/N
			Injection site pain/ injection site pain#	3	20MAY2021	1/3	1	Yes		NA	R (22MAY2021)	N/N
C4591001 1223 12231286/ Placebo	15/F/ WHITE	NERV	Headache/ headache	2	05FEB2021	3/3	1	Yes		NA/TC	R (07FEB2021)	N/N
		GENRL	Fatigue/ fatigue#	3	21MAY2021	1/3	1	Yes		NA	R (23MAY2021)	N/N
			Pyrexia/ fever#	3	21MAY2021	1/2	1	Yes		NA/TC	R (22MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	4	11JUN2021	1/2	1	Yes		NA	R (12JUN2021)	N/N
		Injection site pain/ injection site pain#	4	11JUN2021	1/2	1	Yes		NA	R (12JUN2021)	N/N	
C4591001 1235	13/M/ WHITE	INFECTION	Paronychia/ ingrown toenail infection#	3	24MAY2021	7/15	2	No	O	NA/TC/TCN	R (07JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Cause of Vax Rel <sup>c</sup>	AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
12351235/ Placebo			Skin candida/ cutaneous candidiasis#	3	24MAY2021	7/15	2	No	O	NA/TC	R (07JUN2021)	N/N
		GENRL	Adverse drug reaction/ antibiotic side effect#	3	02JUN2021	16/4	2	No	O	NA	R (05JUN2021)	N/N
C4591001 1235 12351252/ Placebo	13/M/ WHITE	SKIN	Urticaria/ allergic urticaria#	4	27JUN2021	20/3	2	No	O	NA/TC	R (29JUN2021)	N/N
C4591001 1270 12701173/ Placebo	15/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	13MAY2021	1/3	1	Yes		NA	R (15MAY2021)	N/N
			Injection site pain/ Injection Site Pain#	3	13MAY2021	1/2	1	Yes		NA	R (14MAY2021)	N/N
			Pain/ Generalized Body Aches#	3	13MAY2021	1/3	1	Yes		NA	R (15MAY2021)	N/N
C4591001 1270 12701181/ Placebo	15/F/ WHITE	MUSC	Back pain/ Low Back Pain	2	22FEB2021	63/36	1	No	O	NA	R (29MAR2021)	N/N
C4591001 1270 12701188/ Placebo	13/M/ ASIAN	GENRL	Fatigue/ Fatigue#	3	18MAY2021	1/2	1	Yes		NA	R (19MAY2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		NERV	Headache/ Headache#	3	18MAY2021	1/2	1	Yes		NA	R (19MAY2021)	N/N
C4591001 1270 12701200/ BNT162b2 (30 µg)	13/M/ WHITE	INFEC	Anal abscess/ PERIANAL ABSCESS	2	16MAR2021	78/C	3	No	O	NA/TC/TCN	RG	Y/N
C4591001 1270 12701202/ BNT162b2 (30 µg)	15/M/ WHITE	INFEC	Paronychia/ Left finger paronychia	2	17MAR2021	77/9	1	No	O	NA/TC	R (25MAR2021)	N/N
C4591001 1270 12701204/ Placebo	12/M/ NOT REPORTED	GENRL	Chills/ Chills#	3	18MAY2021	2/1	1	Yes		NA/TC	R (18MAY2021)	N/N
			Injection site pain/ Injection site pain#	3	18MAY2021	2/1	1	Yes		NA/TC	R (18MAY2021)	N/N
			Pyrexia/ Fever#	3	18MAY2021	2/1	2	Yes		NA/TC	R (18MAY2021)	N/N
C4591001 1270 12701205/ Placebo	13/F/ MULTIPLE	INFEC	Subcutaneous abscess/ Subcutaneous Tissue Abscess Right Earlobe	1	19DEC2020	5/17	1	No	O	NA/TCN	R (04JAN2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	3	17MAY2021	1/4	1	Yes		NA/TC	R (20MAY2021)	N/N
		SKIN	Ingrowing nail/ Right Ingrown Toenail#	3	09JUN2021	24/22	1	No	O	NA/TC	R (30JUN2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Action:			SAE/Imm AE (Yes/No)
									Cause of AE	Investigational Vaccine Dose/ Subject	Outcome (End Date)	
C4591001 1270 12701206/ Placebo	15/F/ WHITE	GENRL	Fatigue/ FATIGUE#	3	27MAY2021	2/1	2	Yes		NA	R (27MAY2021)	N/N
			Injection site pain/ Injection site pain#	3	27MAY2021	2/1	1	Yes		NA	R (27MAY2021)	N/N
		INJ&P	Ligament sprain/ RIHT WRIST SPRAIN#	4	14JUL2021	29/C	1	No	O	NA/TC/TCN	RG	N/N
C4591001 1270 12701208/ Placebo	14/F/ WHITE	INJ&P	Concussion/ Concussion without loss of consciousness	2	11MAR2021	65/	2	No	O	NA/TCN	R	N/N
			Hand fracture/ Left Middle Finger Middle Phalanx Fracture	2	11MAR2021	65/70	2	No	O	NA/TCN	R (19MAY2021)	N/N
			Hand fracture/ Right Middle Finger Phalanx Fracture	2	11MAR2021	65/70	2	No	O	NA/TCN	R (19MAY2021)	N/N
C4591001 1270 12701213/ Placebo	12/F/ WHITE	GASTR	Abdominal pain/ Chronic Abdominal Pain	2	JAN2021	1/C	1	No	O	NA/TC	N	N/N
		MUSC	Tendonitis/ tendinitis of Left Ankle	2	JAN2021	1/C	1	No	O	NA/TC/TCN	RG	N/N
		GENRL	Fatigue/ Fatigue#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
			Injection site pain/ Injection site pain#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N

16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age													
Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
C4591001 1270 12701216/ Placebo	12/F/ MULTIPLE	NERV	Headache/ Headache#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N	
		NERV	Syncope/ Syncope#	2	17MAY2021	132/1	2	No	O	NA/TCN	R (17MAY2021)	N/N	
C4591001 1270 12701217/ Placebo	12/F/ WHITE	NEOPL	Melanocytic naevus/ Melanocytic Nevus	2	10FEB2021	34/C	1	No	O	NA	N	N/N	
		SKIN	Acne/ Acne Vulgaris	2	10FEB2021	34/C	1	No	O	NA/TC	RG	N/N	
			Seborrheic dermatitis/ Seborrheic Dermatitis to scalp	2	10FEB2021	34/C	1	No	O	NA/TC	RG	N/N	
		GENRL	Injection site pain/ Injection site pain#	3	17MAY2021	1/3	1	Yes		NA	R (19MAY2021)	N/N	
C4591001 1270 12701221/ Placebo	12/F/ WHITE	GENRL	Chills/ Chills#	3	26MAY2021	1/2	1	Yes		NA	R (27MAY2021)	N/N	
		EAR	Ear pain/ Right otalgia#	4	02JUL2021	19/7	1	No	O	NA/TC	R (08JUL2021)	N/N	
C4591001 1270 12701222/ BNT162b2 (30 µg)	14/F/ WHITE	PSYCH	Suicidal ideation/ SUCIDAL IDEATION	2	16FEB2021	40/28	3	No	O	NA/TC/TCN	R (15MAR2021)	Y/N	
C4591001 1270	13/M/ WHITE	GENRL	Pain/ Body Aches#	3	21MAY2021	2/2	1	Yes		NA	R (22MAY2021)	N/N	

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
12701223/ Placebo			Pyrexia/ Fever#	3	21MAY2021	2/2	1	Yes		NA	R (22MAY2021)	N/N
C4591001 1270 12701227/ Placebo	13/M/ ASIAN	MUSC	Myalgia/ Generalized Myalgia#	3	19MAY2021	2/1	1	Yes		NA/TC	R (19MAY2021)	N/N
		NERV	Headache/ Headache#	3	19MAY2021	2/1	1	Yes		NA/TC	R (19MAY2021)	N/N
C4591001 1270 12701228/ Placebo	12/F/ WHITE	RENAL	Dysuria/ Dysuria#	4	09JUN2021	7/3	1	No	O	NA	R (11JUN2021)	N/N
C4591001 1270 12701233/ BNT162b2 (30 µg)	14/F/ WHITE	GASTR	Rectal prolapse/ Rectal Prolapse	2	22FEB2021	28/C	1	No	O	NA/TC	RG	N/N
C4591001 1270 12701236/ Placebo	14/F/ WHITE	PSYCH	Anxiety/ Anxiety	1	11JAN2021	6/C	1	No	O	NA	RG	N/N
C4591001 1270 12701237/ Placebo	13/F/ AMERICAN INDIAN OR ALASKA NATIVE	MUSC	Musculoskeletal chest pain/ Rib pain on right side	1	10FEB2021	35/29	1	No	O	NA	R (10MAR2021)	N/N
		SKIN	Rash/ Rash on Right Foot	1	05APR2021	89/4	1	No	O	NA/TC	R (08APR2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		GASTR	Nausea/ INTERMITTENT NAUSEA#	3	19MAY2021	1/56	2	Yes		NA	R (13JUL2021)	N/N
		GENRL	Chills/ CHILLS#	3	19MAY2021	1/3	1	Yes		NA/TC	R (21MAY2021)	N/N
			Non-cardiac chest pain/ INTERMITTENT NON-CARDIAC CHEST DISCOMFORT#	3	19MAY2021	1/56	2	Yes		NA/TC	R (13JUL2021)	N/N
		NERV	Headache/ INTERMITTENT HEADACHES#	3	19MAY2021	1/56	2	Yes		NA/TC	R (13JUL2021)	N/N
		GENRL	Pyrexia/ Fever#	3	20MAY2021	2/2	1	Yes		NA/TC	R (21MAY2021)	N/N
		GASTR	Abdominal pain upper/ INTERMITTENT STOMACH PAIN#	3	25MAY2021	7/50	2	Yes		NA	R (13JUL2021)	N/N
		GENRL	Fatigue/ FATIGUE#	3	25MAY2021	7/50	3	Yes		NA	R (13JUL2021)	N/N
			Thirst/ INCREASED THIRST#	3	25MAY2021	7/19	1	Yes		NA	R (12JUN2021)	N/N
		METAB	Decreased appetite/ LOSS OF APPETITE#	3	25MAY2021	7/50	2	Yes		NA	R (13JUL2021)	N/N
		INFECTION	Otitis media/ LEFT OTITIS MEDIA#	3	29JUN2021	42/8	1	No	O	NA/TC	R (06JUL2021)	N/N

## 16.2.7.2.1 Listing of Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Action:			SAE/Imm AE (Yes/No)
									Cause of AE	Investigational Vaccine Dose/ Subject	Outcome (End Date)	
C4591001 1270 12701241/ Placebo	13/M/ WHITE	GENRL	Chills/ Chills#	3	19MAY2021	1/2	1	Yes	NA	R (20MAY2021)	N/N	
			Pyrexia/ Fever#	3	19MAY2021	1/2	1	Yes	NA/TC	R (20MAY2021)	N/N	
			NERV Headache/ Headache#	3	19MAY2021	1/2	1	Yes	NA/TC	R (20MAY2021)	N/N	
C4591001 1270 12701244/ Placebo	14/F/ WHITE	GENRL	Injection site pain/ Injection site pain#	3	18MAY2021	1/2	1	Yes	NA/TC	R (19MAY2021)	N/N	

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.  
Note: MedDRA (v24.0) coding dictionary applied.  
Note: \* = prevaccination AE, # = AE occurring on or after subject unblinding, + = new arthralgia after the EUA snapshot.  
Note: For original placebo group subjects, Dose 3 = first dose of BNT162b2 (30 µg), Dose 4 = second dose of BNT162b2 (30 µg).  
a. Relative day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.  
b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.  
c. Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.  
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (17:29) Source Data: adae Table Generation: 08NOV2021 (19:56)  
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2\_unblinded/C4591001\_S\_Peds/adae\_1002\_1\_ped6

**16.2.7.2.2 Listing of Adverse Events Updated After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	Updates from EUA to sBLA <sup>d</sup>
C4591001 1006 10061272/ BNT162b2 (30 µg)	13/F/ BLACK OR AFRICAN AMERICAN	PSYCH	Anxiety/ Worsening of anxiety	1	23DEC2020	8/27	3	No	O	NA/TC/TCN	R (18JAN2021)	Y/N	C3
			Depression/ Worsening of Depression	1	23DEC2020	8/27	3	No	O	NA/TC/TCN	R (18JAN2021)	Y/N	C3
		INJ&P	Contusion/ Contusion left elbow	1	05FEB2021	52/29	1	No	O	NA	R (05MAR2021)	N/N	C2
C4591001 1006 10061290/ BNT162b2 (30 µg)	15/F/ WHITE	INJ&P	Concussion/ Concussion	1	12JAN2021	22/32	2	No	O	NA/TC	R (12FEB2021)	N/N	C2
C4591001 1007 10071497/ BNT162b2 (30 µg)	12/M/ ASIAN	BLOOD	Lymphadenopathy/ swollen lymph node left axilla	2	25DEC2020	4/27	1	Yes		NA	R (20JAN2021)	N/N	C2
C4591001 1007 10071575/ BNT162b2 (30 µg)	15/M/ WHITE	INJ&P	Contusion/ Contusion of Left Arm	1	03JAN2021	19/11	2	No	O	NA/TC	R (13JAN2021)	N/N	C1, C2
C4591001 1007 10071581/ Placebo	15/M/ WHITE	INFEC	Appendicitis/ Appendicitis	2	10MAR2021	63/20	3	No	O	NA/TC	R (29MAR2021)	Y/N	C2, C5

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**16.2.7.2.2 Listing of Adverse Events Updated After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	Updates from EUA to sBLA <sup>d</sup>
C4591001 1007 10071585/ Placebo	12/M/ WHITE	SKIN	Urticaria/ hives; trunk, abdomen, back	2	16JAN2021	10/18	2	Yes		NA/TC	R (02FEB2021)	N/N	C2
C4591001 1007 10071620/ BNT162b2 (30 µg)	12/F/ WHITE	PSYCH	Conversion disorder/ generalized Functional neurologic disorder	2	21JAN2021	2/C	2	No	O	NA/TC	N	Y/N	C1, C2, C4
		GASTR	Gastritis/ Gastritis	2	30JAN2021	11/	2	No	CD	NA/TC	R	N/N	C2
		SKIN	Dermatitis contact/ contact dermatitis bilateral arms	2	12FEB2021	24/	1	No	O	NA/TC	R	N/N	C2
		GASTR	Abdominal pain/ Functional Abdominal Pain	2	28FEB2021	40/C	3	No	O	NA/TC	N	Y/N	C4
			Constipation/ Constipation	2	28FEB2021	40/14	3	No	O	NA/TC	R (13MAR2021)	Y/N	C2
C4591001 1007 10071651/ BNT162b2 (30 µg)	12/M/ WHITE	BLOOD	Lymphadenopathy/ left Cervical lymphadenopathy	2	23FEB2021	29/15	1	No	O	NA	R (09MAR2021)	N/N	C2
C4591001 1009 10091366/ Placebo	14/F/ WHITE	GENRL	Injection site pain/ Mild Injection Site Pain	2	26FEB2021	1/2	1	Yes		NA	R (27FEB2021)	N/N	C5

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**16.2.7.2.2 Listing of Adverse Events Updated After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	Updates from EUA to sBLA <sup>d</sup>
C4591001 1009 10091380/ Placebo	14/M/ WHITE	INJ&P	Clavicle fracture/ Right Clavicle Fracture	1	18JAN2021	21/36	2	No	O	NA/TC	R (22FEB2021)	N/N	C2
C4591001 1009 10091399/ Placebo	12/F/ WHITE	INJ&P	Foot fracture/ Left Fifth Metatarsal Fracture	2	23FEB2021	26/82	2	No	O	NA/TC	R (15MAY2021)	N/N	C2
C4591001 1009 10091406/ Placebo	15/M/ WHITE	MUSC	Joint swelling/ Swilling in bilateral knees	1	25JAN2021	18/36	1	No	O	NA/TC	R (01MAR2021)	N/N	C2
C4591001 1013 10131839/ Placebo	14/F/ WHITE	INJ&P	Concussion/ SPORTS RELATED CONCUSSION	2	01MAR2021	69/C	2	No	O	NA	RG	N/N	C6
C4591001 1039 10391314/ Placebo	14/F/ ASIAN	NEOPL	Fibroadenoma of breast/ Exacerbation of fibroadenoma of right breast	2	06FEB2021	10/60	1	No	O	NA/TCN	R (06APR2021)	N/N	C2, C3, C4
C4591001 1039 10391326/ BNT162b2 (30 µg)	15/M/ ASIAN	PSYCH	Depression/ Depression Exacerbation	1	26JAN2021	16/5	3	No	O	NA/TC/TCN	R (30JAN2021)	Y/N	C4
C4591001 1044 10441304/ BNT162b2 (30 µg)	15/F/ WHITE	SKIN	Rash/ generalized rash	2	25FEB2021	38/3	1	No	O	NA/TC	R (27FEB2021)	N/N	C4, C6

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16.2.7.2.2 Listing of Adverse Events Updated After the EUA Snapshot – All Subjects 12 Through 15 Years of Age														
Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ Investigator AE Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	Updates from EUA to sBLA <sup>d</sup>	
C4591001 1044 10441337/ Placebo	13/M/ WHITE	INJ&P	Humerus fracture/ Broken humerus (right arm)	1	10JAN2021	3/34	2	No	O	NA/TC	R (12FEB2021)	N/N	C2	
C4591001 1057 10571451/ BNT162b2 (30 µg)	12/F/ WHITE	INFEC	Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	1	13JAN2021	2/22	2	No	O	NA/TC	R (03FEB2021)	N/N	C2	
C4591001 1066 10661422/ BNT162b2 (30 µg)	12/M/ WHITE	SKIN	Rash/ rash on torso	1	24DEC2020	3/5	1	No	O	NA	R (28DEC2020)	N/N	C2	
C4591001 1123 11231442/ Placebo	12/M/ WHITE	PSYCH	Depression/ Depression	1	23DEC2020	15/164	2	No	O	NA/TC	R (04JUN2021)	N/N	C2	
C4591001 1126 11261246/ BNT162b2 (30 µg)	13/M/ WHITE	GENRL	Nodule/ Red bump on right index finger at cuticle	2	13JAN2021	22/50	1	No	O	NA	R (03MAR2021)	N/N	C2	
C4591001 1131 11311301/ BNT162b2 (30 µg)	13/M/ WHITE	MUSC	Arthralgia/ sacroiliac joint pain	1	15JAN2021	5/25	2	No	O	NA	R (08FEB2021)	N/N	C2	
		INJ&P	Accident/ skiing accident	2	18FEB2021	14/2	2	No	O	NA/TC/TCN	R (19FEB2021)	N/N	C2	

**16.2.7.2.2 Listing of Adverse Events Updated After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ Investigator AE Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	Updates from EUA to sBLA <sup>d</sup>
		INJ&P	Clavicle fracture/ right clavicle fracture	2	19FEB2021	15/64	2	No	O	NA/TC/TCN	R (23APR2021)	N/N	C2
C4591001 1139 11391246/ Placebo	15/M/ WHITE	MUSC	Arthralgia/ Bilateral knee pain	1	11JAN2021	4/36	2	No	O	NA/TC	R (15FEB2021)	N/N	C2
C4591001 1139 11391248/ BNT162b2 (30 µg)	15/M/ WHITE	INJ&P	Muscle strain/ Abdominal Muscle Strain	2	10MAR2021	41/4	1	No	O	NA	R (13MAR2021)	N/N	C2, C6
C4591001 1142 11421385/ BNT162b2 (30 µg)	15/M/ NOT REPORTED	BLOOD	Lymphadenopathy/ left supraclavicular lymph node swelling	1	07JAN2021	8/8	1	Yes		NA	R (14JAN2021)	N/N	C2
C4591001 1147 11471263/ BNT162b2 (30 µg)	12/M/ WHITE	NEOPL	Hair follicle tumour benign/ Pilomatrixoma	1	2020	1/	1	No	O	NA/TC/TCN	R (09FEB2021)	N/N	C1, C2, C3, C4
C4591001 1150 11501129/ Placebo	12/F/ WHITE	INJ&P	Concussion/ Concussion	2	11JAN2021	63/60	2	No	O	NA	R (11MAR2021)	N/N	C4
C4591001 1270 12701222/ BNT162b2 (30 µg)	14/F/ WHITE	PSYCH	Suicidal ideation/ SUICIDAL IDEATION	2	16FEB2021	40/28	3	No	O	NA/TC/TCN	R (15MAR2021)	Y/N	C2, C3

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**16.2.7.2.2 Listing of Adverse Events Updated After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade Rel <sup>c</sup> AE	Action: Cause Investigational of Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	Updates from EUA to sBLA <sup>d</sup>
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Abbreviations: C = continuing; Dur = duration; Imm = immediate; EUA = emergency use authorization. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v24.0) coding dictionary applied.

- a. Relative day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.
- b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.
- c. Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.
- d. C1 means AE preferred term changed from EUA to sBLA; C2 means AE resolved date or ongoing status , or outcome changed from EUA to sBLA; C3 means AE action changed from EUA to sBLA; C4 means AE causality changed from EUA to sBLA; C5 means AE onset date changed from EUA to sBLA; C6 means minor AE term changed from EUA to sBLA and AE dictionary derived remains the same.

PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (17:29) Source Data: adae Table Generation: 08NOV2021 (19:56)

(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2\_unblinded/C4591001\_S\_Peds/adae\_1002\_1\_c\_ped6

**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1005 10051339/ Placebo	14/F/ WHITE	PSYCH	Anxiety/ anxiety	2	21APR2021	162/C	1	No	O	NA/TC	N	N/N
		MUSC	Myalgia/ generalized myalgia#	3	19MAY2021	3/5	1	Yes		NA	R (23MAY2021)	N/N
C4591001 1005 10051417/ Placebo	13/F/ WHITE	GENRL	Pyrexia/ fever#	4	13AUG2021	1/2	2	Yes		NA	R (14AUG2021)	N/N
C4591001 1005 10051420/ BNT162b2 (30 µg)	12/F/ WHITE	PSYCH	Anxiety/ Anxiety	2	03MAY2021	120/C	1	No	O	NA/TC	N	N/N
			Depression/ Depression	2	03MAY2021	120/C	1	No	O	NA/TC	N	N/N
C4591001 1005 10051427/ Placebo	14/F/ WHITE	GENRL	Chills/ chills#	4	07JUN2021	1/3	2	Yes		NA	R (09JUN2021)	N/N
		MUSC	Myalgia/ generalized myalgia#	4	07JUN2021	1/3	2	Yes		NA	R (09JUN2021)	N/N
C4591001 1005 10051437/ Placebo	15/F/ WHITE	GENRL	Fatigue/ Fatigue#	4	17JUN2021	1/10	2	Yes		NA	R (26JUN2021)	N/N

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## 16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		MUSC	Myalgia/ Generalized myalgia#	4	17JUN2021	1/10	2	Yes		NA	R (26JUN2021)	N/N
C4591001 1005 10051449/ BNT162b2 (30 µg)	14/M/ WHITE	INFEC	Appendicitis/ Appendicitis#	2	28JUN2021	148/2	2	No	O	NA/TCN	R (29JUN2021)	Y/N
C4591001 1005 10051450/ Placebo	14/M/ ASIAN	INJ&P	Hand fracture/ Broken left thumb#	3	10JUN2021	18/37	2	No	O	NA	R (16JUL2021)	N/N
C4591001 1006 10061183/ Placebo	14/M/ MULTIPLE	INJ&P	Hand fracture/ Broken thumb- left	2	12MAY2021	126/36	2	No	O	NA	R (16JUN2021)	N/N
		GENRL	Injection site pain/ Injection Site Tenderness#	3	20MAY2021	1/3	1	Yes		NA	R (22MAY2021)	N/N
C4591001 1006 10061196/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ Injection site tenderness#	3	19MAY2021	1/8	1	Yes		NA	R (26MAY2021)	N/N
C4591001 1006 10061223/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Injection Site Pain#	3	18MAY2021	2/4	1	Yes		NA/TC	R (21MAY2021)	N/N
C4591001 1006 10061226/ Placebo	15/F/ WHITE	PSYCH	Attention deficit hyperactivity disorder/ Attention Deficit	2	24MAR2021	87/C	2	No	O	NA/TC	N	N/N

## 16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1006 10061228/ Placebo	12/F/ WHITE	PSYCH	Hyperactivity Disorder Attention deficit hyperactivity disorder/ Attention Deficit Hyperactivity Disorder	2	24MAR2021	86/C	2	No	O	NA/TC	N	N/N
C4591001 1006 10061253/ Placebo	14/M/ WHITE	INJ&P	Facial bones fracture/ Fractured Nasal Septum#	3	02JUN2021	17/5	1	No	O	NA/TC	R (06JUN2021)	N/N
C4591001 1006 10061258/ BNT162b2 (30 µg)	14/M/ NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	GASTR	Aphthous ulcer/ ORAL CANKERS#	2	27JUN2021	174/9	2	No	O	NA/TC	R (05JUL2021)	N/N
C4591001 1006 10061272/ BNT162b2 (30 µg)	13/F/ BLACK OR AFRICAN AMERICAN	INJ&P	Fall/ Fall	1	05FEB2021	52/1	1	No	O	NA	R (05FEB2021)	N/N
		GENRL	Injection site pain/ Injection site soreness#	2	17MAY2021	1/4	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1006 10061274/ BNT162b2 (30 µg)	14/F/ WHITE	NERV	Migraine/ MIGRAINE HEADACHES	2	APR2021	84/C	2	No	O	NA/TC	N	N/N

**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1006 10061279/ Placebo	13/F/ WHITE	PSYCH	Anxiety/ Worsening of Anxiety	2	MAR2021	56/C	2	No	O	NA/TC	N	N/N
		INJ&P	Ligament sprain/ Left Sprained Ankle	2	26MAR2021	81/C	1	No	O	NA/TC/TCN	N	N/N
		NEOPL	Skin papilloma/ Left Foot Plantar Wart#	4	09JUN2021	3/9	2	No	O	NA/TCN	R (17JUN2021)	N/N
C4591001 1006 10061285/ Placebo	14/F/ WHITE	RENAL	Dysuria/ dysuria	2	31MAY2021	140/51	1	No	O	NA	R (20JUL2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	3	04JUN2021	2/2	2	Yes		NA	R (05JUN2021)	N/N
C4591001 1006 10061286/ BNT162b2 (30 µg)	14/M/ WHITE	INJ&P	Bone contusion/ CONTUSION RIGHT CALCANEUS	2	08MAR2021	57/C	2	No	O	NA/TCN	N	N/N
C4591001 1006 10061292/ Placebo	15/F/ WHITE	INJ&P	Procedural pain/ Post Surgical pain Spinal hardware removal	2	30MAR2021	78/6	3	No	O	NA/TC	R (04APR2021)	N/N
C4591001 1007 10071409/ BNT162b2 (30 µg)	13/M/ ASIAN	GENRL	Fatigue/ fatigue#	2	28MAY2021	2/3	2	Yes		NA	R (30MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1007 10071414/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ pain at injection site#	2	28MAY2021	2/4	1	Yes		NA	R (31MAY2021)	N/N
			Pyrexia/ fever#	2	28MAY2021	2/3	3	Yes		NA/TC	R (30MAY2021)	N/N
			NERV Headache/ headache#	2	28MAY2021	2/3	1	Yes		NA	R (30MAY2021)	N/N
			Chills/ chills#	3	20MAY2021	2/3	2	Yes		NA	R (22MAY2021)	N/N
			Fatigue/ Fatigue#	3	20MAY2021	2/3	3	Yes		NA	R (22MAY2021)	N/N
C4591001 1007 10071480/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Injection site pain#	3	17MAY2021	1/8	1	Yes		NA	R (24MAY2021)	N/N
			GENRL Injection site pain/ Injection site pain#	4	08JUN2021	1/3	1	Yes		NA	R (10JUN2021)	N/N
			GENRL Pyrexia/ fever#	4	09JUN2021	2/2	2	Yes		NA/TC	R (10JUN2021)	N/N
			NERV Headache/ headache#	4	09JUN2021	2/2	2	Yes		NA/TC	R (10JUN2021)	N/N
			MUSC Neck pain/ neck pain#	4	11JUN2021	4/C	2	No	O	NA	N	N/N
			INFEC Herpes zoster/ shingles#	4	18JUN2021	11/13	2	No	O	NA	R (30JUN2021)	N/N
			MUSC Pain in extremity/ Deltoid of left arm pain#	4	20JUN2021	13/4	2	No	O	NA	R (23JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1007 10071483/ Placebo	15/F/ WHITE	GENRL	Injection site pain/ Injection site pain#	3	30MAR2021	1/5	1	Yes		NA	R (03APR2021)	N/N
C4591001 1007 10071484/ Placebo	13/F/ WHITE	GENRL	Fatigue/ fatigue#	3	20MAY2021	2/34	1	Yes		NA	R (22JUN2021)	N/N
			Injection site pain/ injection site pain#	3	20MAY2021	2/1	1	Yes		NA	R (20MAY2021)	N/N
			Pyrexia/ subjective fever#	3	20MAY2021	2/3	1	Yes		NA	R (22MAY2021)	N/N
		MUSC	Myalgia/ generalized muscle aches#	3	20MAY2021	2/3	1	Yes		NA	R (22MAY2021)	N/N
C4591001 1007 10071499/ Placebo	14/M/ WHITE	MUSC	Arthralgia/ left wrist pain+	2	01MAY2021	131/3	1	No	O	NA/TC/TCN	R (03MAY2021)	N/N
C4591001 1007 10071505/ Placebo	12/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	03JUN2021	2/2	1	Yes		NA	R (04JUN2021)	N/N
		MUSC	Pain in extremity/ Right Arm Pain#	3	03JUN2021	2/4	1	Yes		NA	R (06JUN2021)	N/N
		GENRL	Injection site pain/ injection site pain#	4	23JUN2021	1/3	1	Yes		NA	R (25JUN2021)	N/N
		GASTR	Nausea/ nausea#	4	24JUN2021	2/2	1	Yes		NA	R (25JUN2021)	N/N
		GENRL	Pyrexia/ fever 101#	4	24JUN2021	2/2	2	Yes		NA/TC	R (25JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		NERV	Dizziness/ lightheadedness#	4	24JUN2021	2/2	1	Yes		NA/TCN	R (25JUN2021)	N/N
			Headache/ headache#	4	24JUN2021	2/2	2	Yes		NA/TC	R (25JUN2021)	N/N
		NERV	Somnolence/ Excessive Sleepiness#	4	08JUL2021	16/15	3	No	O	NA	R (22JUL2021)	Y/N
C4591001 1007 10071509/ Placebo	15/F/ WHITE	MUSC	Pain in extremity/ Right Arm Pain#	3	21MAY2021	2/3	1	Yes		NA/TC	R (23MAY2021)	N/N
C4591001 1007 10071511/ Placebo	15/M/ WHITE	NERV	Headache/ Headache#	3	18MAY2021	1/2	1	Yes		NA	R (19MAY2021)	N/N
		MUSC	Pain in extremity/ Left arm pain#	3	19MAY2021	2/2	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1007 10071516/ Placebo	15/M/ WHITE	GENRL	Chills/ Chills#	3	19MAY2021	2/2	1	Yes		NA	R (20MAY2021)	N/N
			Pyrexia/ Fever#	3	19MAY2021	2/2	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1007 10071519/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	31MAR2021	1/2	2	Yes		NA	R (01APR2021)	N/N
C4591001 1007 10071531/ Placebo	14/F/ WHITE	NERV	Headache/ Headache#	3	26MAY2021	2/1	2	Yes		NA/TC	R (26MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1007 10071547/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ injection site pain#	3	22JUN2021	29/3	1	Yes		NA	R (24JUN2021)	N/N
		MUSC	Myalgia/ muscle aches to legs#	4	22JUN2021	1/3	1	Yes		NA	R (24JUN2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	3	20MAY2021	1/3	1	Yes		NA	R (22MAY2021)	N/N
		GENRL	Injection site erythema/ Injection site redness#	3	21MAY2021	2/4	1	Yes		NA	R (24MAY2021)	N/N
C4591001 1007 10071559/ Placebo	14/F/ WHITE	GENRL	Fatigue/ fatigue#	3	28MAY2021	2/3	2	Yes		NA	R (30MAY2021)	N/N
		NERV	Dizziness/ dizziness#	3	28MAY2021	2/3	1	Yes		NA	R (30MAY2021)	N/N
			Headache/ headache#	3	28MAY2021	2/3	2	Yes		NA	R (30MAY2021)	N/N
		NERV	Headache/ headache#	3	05JUN2021	10/1	2	No	O	NA/TC	R (05JUN2021)	N/N
		GENRL	Chills/ chills#	4	17JUN2021	1/2	1	Yes		NA/TC	R (18JUN2021)	N/N
			Injection site pain/ injection site pain#	4	17JUN2021	1/3	1	Yes		NA	R (19JUN2021)	N/N
	Pyrexia/ fever 101.9#	4	17JUN2021	1/2	2	Yes		NA/TC	R (18JUN2021)	N/N		

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Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1007 10071562/ Placebo	12/F/ WHITE	MUSC	Myalgia/ generalized muscle pain#	4	17JUN2021	1/2	2	Yes		NA/TC	R (18JUN2021)	N/N
		NERV	Headache/ headache#	4	17JUN2021	1/2	1	Yes		NA	R (18JUN2021)	N/N
		GENRL	Fatigue/ fatigue#	3	18MAY2021	2/1	1	Yes		NA	R (18MAY2021)	N/N
		INV	Body temperature increased/ elevated body temp#	3	18MAY2021	2/1	2	Yes		NA/TC	R (18MAY2021)	N/N
		MUSC	Myalgia/ generalized muscle aches#	3	18MAY2021	2/1	1	Yes		NA	R (18MAY2021)	N/N
		INV	Body temperature increased/ elevated body temp 100.0#	4	07JUN2021	1/2	2	Yes		NA/TC	R (08JUN2021)	N/N
		GENRL	Fatigue/ fatigue#	4	08JUN2021	2/1	2	Yes		NA	R (08JUN2021)	N/N
C4591001 1007 10071581/ Placebo	15/M/ WHITE	MUSC	Myalgia/ generalized muscle aches#	4	08JUN2021	2/1	1	Yes		NA	R (08JUN2021)	N/N
		GENRL	Fatigue/ fatigue#	4	15JUN2021	2/2	2	Yes		NA	R (16JUN2021)	N/N
			Injection site pain/ injection site pain#	4	15JUN2021	2/2	1	Yes		NA	R (16JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		MUSC	Myalgia/ generalized muscle aches#	4	15JUN2021	2/2	2	Yes		NA/TC	R (16JUN2021)	N/N
C4591001 1007 10071583/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ injection site pain#	4	09JUN2021	1/3	2	Yes		NA	R (11JUN2021)	N/N
		NERV	Headache/ headache#	4	10JUN2021	2/1	1	Yes		NA	R (10JUN2021)	N/N
C4591001 1007 10071586/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ Injection site pain#	3	02JUN2021	2/3	1	Yes		NA	R (04JUN2021)	N/N
C4591001 1007 10071595/ Placebo	13/F/ WHITE	NERV	Presyncope/ Vaso-vagal response	2	30MAR2021	71/1	1	No	O	NA/TCN	R (30MAR2021)	N/N
C4591001 1007 10071596/ Placebo	13/M/ WHITE	GENRL	Fatigue/ fatigue#	3	24MAY2021	1/5	2	Yes		NA	R (28MAY2021)	N/N
		NERV	Headache/ headache#	3	24MAY2021	1/5	2	Yes		NA	R (28MAY2021)	N/N
		GENRL	Pyrexia/ fever#	3	25MAY2021	2/4	1	Yes		NA	R (28MAY2021)	N/N
		MUSC	Myalgia/ muscle aches#	3	25MAY2021	2/4	2	Yes		NA	R (28MAY2021)	N/N
C4591001 1007 10071600/ Placebo	12/F/ WHITE	PSYCH	Depression/ depression#	2	17MAY2021	119/C	2	No	O	NA/TC	RG	Y/N

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C4591001 1007 10071614/ Placebo	14/M/ WHITE	GENRL	Suicidal ideation/ Suicidal Ideation#	2	17MAY2021	119/5	3	No	O	NA/TC/TCN	R (21MAY2021)	Y/N
			Injection site pain/ injection site soreness#	4	28JUN2021	1/4	1	Yes		NA	R (01JUL2021)	N/N
			Chills/ chills#	4	29JUN2021	2/1	1	Yes		NA	R (29JUN2021)	N/N
			Fatigue/ fatigue#	4	29JUN2021	2/3	1	Yes		NA	R (01JUL2021)	N/N
			Pyrexia/ fever 101.9#	4	29JUN2021	2/3	2	Yes		NA	R (01JUL2021)	N/N
C4591001 1007 10071617/ Placebo	15/F/ WHITE	NERV	Headache/ headache#	4	29JUN2021	2/1	1	Yes		NA	R (29JUN2021)	N/N
			PSYCH	Anxiety/ worsening of Anxiety	2	15FEB2021	27/C	2	No	O	NA/TC	N
C4591001 1007 10071620/ BNT162b2 (30 µg)	12/F/ WHITE	PSYCH	Obsessive- compulsive disorder/ worsening of Obsessive Compulsive Disorder	2	15FEB2021	27/C	2	No	O	NA/TC	N	N/N
			PSYCH	Anxiety/ worsening anxiety	2	30JAN2021	11/C	2	No	O	NA/TC/TCN	N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1007 10071623/ Placebo	13/M/ WHITE	GASTR	Constipation/ constipation	2	13MAR2021	53/C	2	No	O	NA/TC	RG	N/N
		MUSC	Tendonitis/ right wrist tendonitis	2	15FEB2021	26/176	2	No	O	NA/TC	RS (09AUG2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	01JUN2021	1/2	1	Yes		NA	R (02JUN2021)	N/N
C4591001 1007 10071624/ Placebo	13/M/ WHITE		Injection site pain/ Injection site pain#	3	01JUN2021	1/3	1	Yes		NA	R (03JUN2021)	N/N
		MUSC	Pain in extremity/ left Arm Pain#	3	20MAY2021	2/2	1	Yes		NA	R (21MAY2021)	N/N
C4591001 1007 10071625/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ Injection Site Arm Pain#	3	20MAY2021	2/2	1	Yes		NA	R (21MAY2021)	N/N
C4591001 1007 10071632/ Placebo	13/F/ WHITE		Pyrexia/ fever#	3	20MAY2021	2/1	1	Yes		NA/TC	R (20MAY2021)	N/N
		GASTR	Nausea/ Nausea#	3	19MAY2021	2/1	1	Yes		NA	R (19MAY2021)	N/N
		GENRL	Pain/ Body ache#	3	19MAY2021	2/1	1	Yes		NA	R (19MAY2021)	N/N
		MUSC	Pain in extremity/ Arm pain#	3	19MAY2021	2/4	1	Yes		NA	R (22MAY2021)	N/N
		NERV	Headache/ Headache#	3	19MAY2021	2/1	1	Yes		NA	R (19MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1007 10071640/ Placebo	14/F/ WHITE	GASTR	Nausea/ nausea#	4	09JUN2021	2/1	1	Yes		NA	R (09JUN2021)	N/N
		GENRL	Pain/ generalized body aches#	4	09JUN2021	2/1	2	Yes		NA/TC	R (09JUN2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	3	03JUN2021	1/2	1	Yes		NA	R (04JUN2021)	N/N
		GENRL	Chills/ Chills#	4	22JUN2021	1/2	1	Yes		NA	R (23JUN2021)	N/N
		GENRL	Pyrexia/ fever#	4	22JUN2021	1/2	1	Yes		NA/TC/TCN	R (23JUN2021)	N/N
C4591001 1007 10071642/ BNT162b2 (30 µg)	15/M/ WHITE	NERV	Headache/ headache#	4	22JUN2021	1/2	2	Yes		NA/TC	R (23JUN2021)	N/N
		GENRL	Fatigue/ fatigue#	2	28MAY2021	2/2	2	Yes		NA	R (29MAY2021)	N/N
		GENRL	Pain/ body aches#	2	28MAY2021	2/2	2	Yes		NA	R (29MAY2021)	N/N
		GENRL	Pyrexia/ fever 103.5#	2	28MAY2021	2/2	3	Yes		NA/TC	R (29MAY2021)	N/N
		NERV	Dizziness/ dizziness#	2	28MAY2021	2/2	1	Yes		NA	R (29MAY2021)	N/N
C4591001 1007	13/M/ WHITE	NERV	Headache/ headache#	2	28MAY2021	2/2	1	Yes		NA	R (29MAY2021)	N/N
		NERV	Headache/ Headache#	4	15JUN2021	1/2	2	Yes		NA/TC	R (16JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
10071650/ Placebo		GENRL	Chest discomfort/ chest tightness#	4	16JUN2021	2/1	1	No	O	NA/TC	R (16JUN2021)	N/N
			Chills/ chills#	4	16JUN2021	2/1	1	Yes		NA/TC	R (16JUN2021)	N/N
			Fatigue/ fatigue#	4	16JUN2021	2/1	1	Yes		NA/TC	R (16JUN2021)	N/N
			Injection site pain/ injection site pain#	4	16JUN2021	2/1	1	Yes		NA/TC	R (16JUN2021)	N/N
		INV	Body temperature increased/ elevated body temperature unknown temp#	4	16JUN2021	2/1	1	Yes		NA/TC	R (16JUN2021)	N/N
		MUSC	Myalgia/ generalized muscle aches#	4	16JUN2021	2/1	2	Yes		NA/TC	R (16JUN2021)	N/N
C4591001 1007 10071652/ Placebo	12/F/ WHITE	GENRL	Injection site erythema/ Erythema at injection site#	4	21JUN2021	1/2	1	Yes		NA	R (22JUN2021)	N/Y
C4591001 1007 10071658/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ injection site pain#	4	07JUN2021	1/4	1	Yes		NA/TC	R (10JUN2021)	N/N
			Malaise/ malaise#	4	07JUN2021	1/4	3	Yes		NA/TC	R (10JUN2021)	N/N
			Pyrexia/ fever#	4	07JUN2021	1/3	1	Yes		NA/TC	R (09JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1007 10071660/ Placebo	12/M/ WHITE	MUSC	Myalgia/ generalized myalgia#	4	07JUN2021	1/4	3	Yes		NA/TC	R (10JUN2021)	N/N
		MUSC	Musculoskeletal chest pain/ anterior chest wall pain#	4	08JUN2021	2/1	3	Yes		NA/TC	R (08JUN2021)	N/N
		NERV	Headache/ headache#	4	08JUN2021	2/3	2	Yes		NA/TC	R (10JUN2021)	N/N
		GENRL	Injection site pain/ injection site pain#	3	02JUN2021	1/3	2	Yes		NA	R (04JUN2021)	N/N
		GENRL	Chills/ chills#	3	03JUN2021	2/2	1	Yes		NA	R (04JUN2021)	N/N
			Pyrexia/ fever 101.4#	3	03JUN2021	2/2	2	Yes		NA	R (04JUN2021)	N/N
		GENRL	Injection site pain/ injection site pain#	4	24JUN2021	1/2	1	Yes		NA	R (25JUN2021)	N/Y
C4591001 1008 10081761/ Placebo	15/F/ WHITE	GENRL	Fatigue/ fatigue#	4	25JUN2021	2/2	2	Yes		NA	R (26JUN2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	05APR2021	1/2	1	Yes		NA	R (06APR2021)	N/N
C4591001 1008 10081781/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ injection site pain#	4	10JUN2021	2/3	1	Yes		NA	R (12JUN2021)	N/N
			Injection site reaction/	4	10JUN2021	2/3	1	Yes		NA	R (12JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1008 10081788/ Placebo	13/F/ WHITE	GENRL	injection site fatigue# Injection site pain/ injection site pain#	3	13MAY2021	1/2	1	Yes		NA	R (14MAY2021)	N/N
C4591001 1008 10081801/ Placebo	15/F/ WHITE	GENRL	Fatigue/ Fatigue#	4	08JUN2021	2/2	1	Yes		NA	R (09JUN2021)	N/N
C4591001 1008 10081808/ Placebo	13/M/ ASIAN	GENRL	Fatigue/ Fatigue#	3	18MAY2021	2/2	1	Yes		NA	R (19MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	08JUN2021	2/2	1	Yes		NA	R (09JUN2021)	N/N
C4591001 1008 10081812/ Placebo	14/M/ WHITE	NERV	Headache/ headache#	3	14MAY2021	2/2	2	Yes		NA/TC	R (15MAY2021)	N/N
C4591001 1008 10081837/ Placebo	12/M/ WHITE	GENRL	Fatigue/ Fatigue#	3	20MAY2021	2/2	2	Yes		NA	R (21MAY2021)	N/N
			Pain/ body aches#	3	20MAY2021	2/2	2	Yes		NA/TC	R (21MAY2021)	N/N
		NERV	Headache/ headache#	3	20MAY2021	2/2	2	Yes		NA/TC	R (21MAY2021)	N/N
C4591001 1008	12/M/ WHITE	GASTR	Nausea/ nausea#	3	19MAY2021	1/2	1	Yes		NA	R (20MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
10081844/ Placebo		GENRL	Pain/ body aches#	3	20MAY2021	2/1	1	Yes		NA	R (20MAY2021)	N/N
		NERV	Headache/ headache#	3	20MAY2021	2/1	1	Yes		NA/TC	R (20MAY2021)	N/N
C4591001 1008 10081863/ Placebo	13/F/ ASIAN	GENRL	Pain/ Body Aches#	4	08JUN2021	2/2	1	Yes		NA	R (09JUN2021)	N/N
		NERV	Headache/ Headache#	4	08JUN2021	2/2	1	Yes		NA	R (09JUN2021)	N/N
C4591001 1008 10081877/ Placebo	14/M/ WHITE	GENRL	Fatigue/ fatigue#	3	17MAY2021	1/3	2	Yes		NA	R (19MAY2021)	N/N
		GENRL	Pain/ body aches#	3	18MAY2021	2/2	2	Yes		NA	R (19MAY2021)	N/N
C4591001 1008 10081887/ Placebo	12/F/ WHITE	GENRL	Chills/ chills#	3	14MAY2021	2/4	1	Yes		NA	R (17MAY2021)	N/N
		NERV	Headache/ headache#	3	14MAY2021	2/4	2	Yes		NA	R (17MAY2021)	N/N
		SKIN	Hyperhidrosis/ sweating#	3	14MAY2021	2/4	1	Yes		NA	R (17MAY2021)	N/N
C4591001 1008 10081892/ Placebo	14/M/ AMERICAN INDIAN OR ALASKA NATIVE	GENRL	Injection site pain/ injection site pain#	3	25MAY2021	1/5	1	Yes		NA	R (29MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1008 10081913/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ injection site pain#	2	16MAY2021	109/4	1	Yes		NA	R (19MAY2021)	N/N
C4591001 1008 10081931/ Placebo	12/M/ ASIAN	INFEC	Cellulitis/ Cellulitis left leg	2	15MAR2021	43/5	1	No	O	NA/TC	R (19MAR2021)	N/N
C4591001 1008 10081933/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ injection site pain#	4	08JUN2021	2/2	1	Yes		NA	R (09JUN2021)	N/N
C4591001 1009 10091229/ Placebo	12/F/ WHITE	GENRL	Pain/ Body Aches following vaccination#	3	22MAY2021	2/2	2	Yes		NA/TC	R (23MAY2021)	N/N
C4591001 1009 10091294/ Placebo	15/F/ WHITE	GENRL	Pain/ body aches#	3	06APR2021	1/2	1	Yes		NA	R (07APR2021)	N/N
C4591001 1009 10091301/ Placebo	15/F/ WHITE	INJ&P	Arthropod bite/ spider bite#	4	22JUL2021	32/15	2	No	O	NA/TC	R (05AUG2021)	N/N
C4591001 1009 10091305/ Placebo	15/F/ WHITE	BLOOD	Lymphadenitis/ Right Axillary Adenitis#	3	24MAR2021	6/24	2	Yes		NA/TC	R (16APR2021)	N/N
C4591001 1009 10091326/ Placebo	12/F/ WHITE	GENRL	Injection site pain/ Sore (pain) left deltoid- at injection site#	4	26JUN2021	2/1	1	Yes		NA	R (26JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1009 10091338/ Placebo	15/F/ WHITE	NERV	Headache/ headache#	4	26JUN2021	2/1	1	Yes		NA	R (26JUN2021)	N/N
		SURG	Wisdom teeth removal/ Wisdom Teeth Removal	1	08JUN2021	177/1	2	No	O	NA/TC	R (08JUN2021)	N/N
		GASTR	Mouth ulceration/ Mouth Ulcer	1	16JUN2021	185/6	2	No	O	NA/TC	R (21JUN2021)	N/N
C4591001 1009 10091341/ Placebo	13/M/ WHITE	GENRL	Pain/ body aches#	3	03JUL2021	2/1	1	Yes		NA	R (03JUL2021)	N/N
C4591001 1009 10091357/ Placebo	15/M/ WHITE	CONG	Spine malformation/ congenital vertebral pedicle hypoplasia	2	12FEB2021	39/C	1	No	O	NA	N	N/N
C4591001 1009 10091365/ Placebo	12/M/ WHITE	GENRL	Pain/ body aches#	4	06APR2021	2/2	1	Yes		NA	R (07APR2021)	N/N
		NERV	Headache/ headache#	4	06APR2021	2/2	1	Yes		NA	R (07APR2021)	N/N
		INJ&P	Upper limb fracture/ right arm fracture	2	19MAR2021	60/C	2	No	O	NA/TC	RG	N/N
C4591001 1009 10091379/ Placebo	13/F/ WHITE	INJ&P	Contusion/ BRUISED KNEE, LEFT	2	22MAR2021	68/19	2	No	O	NA/TC	R (09APR2021)	N/N
		SKIN	Ingrowing nail/ bilateral great toe ingrown toenail#	3	03JUN2021	16/C	1	No	O	NA/TC	N	N/N

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Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1009 10091382/ Placebo	14/F/ WHITE	GASTR	Nausea/ nausea#	3	15MAY2021	2/3	1	Yes		NA	R (17MAY2021)	N/N
		MUSC	Myalgia/ generalized muscle pain#	3	15MAY2021	2/6	1	Yes		NA	R (20MAY2021)	N/N
		NERV	Dizziness/ dizziness#	3	15MAY2021	2/2	1	Yes		NA	R (16MAY2021)	N/N
		RESP	Rhinorrhoea/ rhinorrhea#	3	15MAY2021	2/3	1	Yes		NA	R (17MAY2021)	N/N
		GENRL	Chills/ chills#	4	03JUN2021	2/1	1	Yes		NA	R (03JUN2021)	N/N
C4591001 1009 10091400/ Placebo	12/M/ WHITE	SKIN	Eczema/ Eczema generalized	2	02APR2021	50/3	2	No	O	NA	R (04APR2021)	N/N
		SKIN	Urticaria/ Urticaria generalized	2	07APR2021	55/8	3	No	O	NA/TC	R (14APR2021)	N/N
C4591001 1009 10091401/ Placebo	12/M/ WHITE	EAR	Motion sickness/ motion sickness#	3	08AUG2021	7/1	1	No	O	NA	R (08AUG2021)	N/N
C4591001 1009 10091405/ Placebo	15/F/ WHITE	BLOOD	Lymphadenopathy/ left axillary adenopathy#	4	20AUG2021	2/C	1	Yes		NA	N	N/N
		GENRL	Fatigue/ fatigue#	4	20AUG2021	2/2	2	Yes		NA	R (21AUG2021)	N/N

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C4591001 1009 10091406/ Placebo	15/M/ WHITE	GENRL	Pyrexia/ fever#	4	20AUG2021	2/1	1	Yes		NA/TC	R (20AUG2021)	N/N	
			NERV	Headache/ headache#	4	20AUG2021	2/2	1	Yes		NA	R (21AUG2021)	N/N
			Fatigue/ fatigue#	4	20AUG2021	2/2	2	Yes			NA	R (21AUG2021)	N/N
			NERV	Pyrexia/ fever#	4	20AUG2021	2/2	1	Yes		NA	R (21AUG2021)	N/N
C4591001 1009 10091409/ BNT162b2 (30 µg)	14/F/ WHITE	INJ&P	Headache/ headache#	4	20AUG2021	2/2	1	Yes		NA	R (21AUG2021)	N/N	
			Procedural pain/ Post Surgical Pain	2	22JUL2021	171/C	2	No	O		NA/TC	N	N/N
C4591001 1009 10091413/ BNT162b2 (30 µg)	13/F/ WHITE	MUSC	Musculoskeletal chest pain/ bilateral rib pain	2	05FEB2021	3/1	2	Yes		NA/TC	R (05FEB2021)	N/N	
			INJ&P	Femur fracture/ Right Intertrochanteric Femur Fracture	2	13MAR2021	39/4	3	No	O	NA/TC/TCN	R (16MAR2021)	Y/N
			INJ&P	Procedural pain/ Post Surgical Right Leg Pain	2	16MAR2021	42/15	2	No	O		NA/TC	R (30MAR2021)
C4591001 1016	12/M/ WHITE	NERV	Syncope/ syncope	2	09APR2021	151/1	2	No	O	NA	R (09APR2021)	N/N	

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10161327/ Placebo		NERV	Epilepsy/ epilepsy#	4	29JUN2021	8/C	2	No	O	NA	N	Y/N
C4591001 1016 10161329/ Placebo	14/M/ WHITE	INJ&P	Wound/ left foot puncture wound#	4	04JUL2021	26/21	1	No	O	NA	R (24JUL2021)	N/N
		INFEC	Cellulitis/ cellulitis of left foot#	4	06JUL2021	28/11	1	No	O	NA/TC	R (16JUL2021)	N/N
C4591001 1016 10161353/ Placebo	13/F/ WHITE	GENRL	Chills/ chills#	3	25MAY2021	2/2	2	Yes		NA	R (26MAY2021)	N/N
			Fatigue/ fatigue#	3	25MAY2021	2/2	2	Yes		NA	R (26MAY2021)	N/N
			Injection site pain/ left deltoid injection site soreness#	3	25MAY2021	2/2	1	Yes		NA	R (26MAY2021)	N/N
		GENRL	Chills/ chills#	4	14JUN2021	1/2	2	Yes		NA/TC	R (15JUN2021)	N/N
			Injection site pain/ injection site pain#	4	14JUN2021	1/4	1	Yes		NA/TC	R (17JUN2021)	N/N
			Pain/ body aches#	4	14JUN2021	1/2	1	Yes		NA/TC	R (15JUN2021)	N/N
			Pyrexia/ fever#	4	14JUN2021	1/2	1	Yes		NA/TC	R (15JUN2021)	N/N
		NERV	Headache/ headache#	4	14JUN2021	1/2	1	Yes		NA/TC	R (15JUN2021)	N/N

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Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1016 10161366/ Placebo	12/M/ WHITE	GASTR	Vomiting/ vomiting#	4	08JUL2021	2/2	1	Yes		NA	R (09JUL2021)	N/N
C4591001 1016 10161371/ Placebo	12/F/ WHITE	GENRL	Fatigue/ fatigue#	4	15JUN2021	2/3	1	Yes		NA	R (17JUN2021)	N/N
			Pyrexia/ fever, low grade#	4	15JUN2021	2/1	1	Yes		NA/TC	R (15JUN2021)	N/N
C4591001 1039 10391246/ Placebo	15/M/ WHITE	GENRL	Fatigue/ fatigue#	4	19MAR2021	2/2	1	Yes		NA	R (20MAR2021)	N/N
			Pyrexia/ fever#	4	19MAR2021	2/2	1	Yes		NA	R (20MAR2021)	N/N
C4591001 1039 10391251/ Placebo	15/F/ ASIAN	GENRL	Fatigue/ Fatigue#	4	25FEB2021	1/3	1	Yes		NA	R (27FEB2021)	N/N
		NERV	Headache/ Headache#	4	25FEB2021	1/3	1	Yes		NA	R (27FEB2021)	N/N
C4591001 1039 10391258/ Placebo	13/F/ WHITE	GENRL	Pyrexia/ Fever#	4	01JUN2021	1/2	1	Yes		NA/TC	R (02JUN2021)	N/N
		NERV	Headache/ Headache#	4	01JUN2021	1/2	1	Yes		NA/TC	R (02JUN2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	02JUN2021	2/2	1	Yes		NA/TC	R (03JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1039 10391259/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ injection site pain#	3	14MAY2021	1/8	1	Yes		NA/TC	R (21MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	3	15MAY2021	2/1	1	Yes		NA/TC	R (15MAY2021)	N/N
		GENRL	Injection site pain/ injection site pain#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/Y
		GENRL	Pyrexia/ fever#	4	05JUN2021	2/3	1	Yes		NA/TC	R (07JUN2021)	N/N
		GENRL	Fatigue/ fatigue#	4	06JUN2021	3/1	1	Yes		NA/TC	R (06JUN2021)	N/N
		NERV	Headache/ headache#	4	06JUN2021	3/1	1	Yes		NA/TC	R (06JUN2021)	N/N
C4591001 1039 10391264/ Placebo	12/F/ ASIAN	MUSC	Myalgia/ General muscle aches#	3	25MAY2021	2/3	1	Yes		NA	R (27MAY2021)	N/N
C4591001 1039 10391266/ Placebo	12/M/ WHITE	GENRL	Fatigue/ Fatigue#	4	04JUN2021	2/2	1	Yes		NA	R (05JUN2021)	N/N
			Pain/ Body ache#	4	04JUN2021	2/2	1	Yes		NA/TC	R (05JUN2021)	N/N
			Pyrexia/ Fever - max 100F#	4	04JUN2021	2/2	1	Yes		NA/TC	R (05JUN2021)	N/N
		MUSC	Myalgia/ Left arm muscle ache#	4	04JUN2021	2/2	1	Yes		NA	R (05JUN2021)	N/N
C4591001 1039	13/F/ WHITE	GENRL	Pyrexia/ Fever - up to 102.5#	3	14MAY2021	2/2	3	Yes		NA	R (15MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
10391268/ Placebo												
C4591001 1039 10391270/ Placebo	13/F/ WHITE	RESP	Epistaxis/ Epistaxis	1	23DEC2020	15/1	1	No	O	NA	R (23DEC2020)	N/N
		GENRL	Injection site pain/ Injection site pain#	3	13MAY2021	1/2	1	Yes		NA/TC	R (14MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	3	14MAY2021	2/3	1	Yes		NA	R (16MAY2021)	N/N
			Pyrexia/ Fever#	3	14MAY2021	2/1	1	Yes		NA/TC	R (14MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	4	04JUN2021	2/3	1	Yes		NA/TC	R (06JUN2021)	N/N
			Pyrexia/ fever#	4	04JUN2021	2/2	1	Yes		NA/TC	R (05JUN2021)	N/N
C4591001 1039 10391271/ Placebo	14/F/ WHITE	NERV	Headache/ Headache#	3	14MAY2021	2/1	2	Yes		NA/TC	R (14MAY2021)	N/N
		NERV	Headache/ headache#	4	04JUN2021	2/1	2	Yes		NA/TC	R (04JUN2021)	N/N
C4591001 1039 10391273/ Placebo	12/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	14MAY2021	2/1	1	Yes		NA	R (14MAY2021)	N/N
			Injection site pain/ Injection site soreness#	3	14MAY2021	2/2	1	Yes		NA	R (15MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1039 10391274/ Placebo	13/M/ WHITE	IMMUN	Food allergy/ exacerbation of pineapple food allergy#	4	01JUL2021	28/1	1	No	O	NA/TC	R (01JUL2021)	N/N
		RESP	Upper-airway cough syndrome/ post nasal drip#	4	01JUL2021	28/6	1	No	O	NA/TC	R (06JUL2021)	N/N
C4591001 1039 10391279/ Placebo	14/F/ WHITE	GENRL	Injection site pain/ injection site pain#	3	17MAY2021	1/3	1	Yes		NA/TC	R (19MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	3	18MAY2021	2/2	1	Yes		NA	R (19MAY2021)	N/N
		GENRL	Chills/ Chills#	4	07JUN2021	1/2	1	Yes		NA/TC	R (08JUN2021)	N/N
			Fatigue/ Fatigue#	4	07JUN2021	1/2	1	Yes		NA/TC/TCN	R (08JUN2021)	N/N
			Injection site pain/ Injection site pain#	4	07JUN2021	1/2	1	Yes		NA	R (08JUN2021)	N/N
			Pain/ Body aches#	4	07JUN2021	1/2	1	Yes		NA/TC	R (08JUN2021)	N/N
C4591001 1039 10391280/ Placebo	13/F/ WHITE	NERV	Presyncope/ Vasovagal episode	2	04FEB2021	29/1	1	No	O	NA	R (04FEB2021)	N/N
		GENRL	Injection site pain/ Injection site soreness#	3	15MAY2021	2/4	1	Yes		NA	R (18MAY2021)	N/N
C4591001 1039	15/M/ WHITE	GENRL	Injection site pain/ Injection site soreness#	3	13MAY2021	1/3	1	Yes		NA	R (15MAY2021)	N/N

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Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Cause of Vax Rel <sup>c</sup> AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
10391283/ Placebo		GENRL	Fatigue/ Fatigue#	3	14MAY2021	2/3	2	Yes	NA	R (16MAY2021)	N/N
		NERV	Headache/ Headache#	3	14MAY2021	2/3	2	Yes	NA	R (16MAY2021)	N/N
C4591001 1039 10391285/ Placebo	13/F/ WHITE	GASTR	Nausea/ nausea#	3	14MAY2021	1/2	1	Yes	NA	R (15MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	3	14MAY2021	1/2	1	Yes	NA	R (15MAY2021)	N/N
		GENRL	Injection site pain/ injection site pain#	3	15MAY2021	2/1	1	Yes	NA	R (15MAY2021)	N/N
		GASTR	Nausea/ nausea#	4	04JUN2021	1/2	1	Yes	NA	R (05JUN2021)	N/N
		GENRL	Pyrexia/ fever#	4	04JUN2021	1/2	1	Yes	NA	R (05JUN2021)	N/N
		MUSC	Arthralgia/ Generalized Arthralgia##	4	04JUN2021	1/2	1	Yes	NA	R (05JUN2021)	N/N
			Myalgia/ muscle aches#	4	04JUN2021	1/2	1	Yes	NA	R (05JUN2021)	N/N
C4591001 1039 10391287/ Placebo	14/F/ WHITE	GENRL	Fatigue/ fatigue#	3	13MAY2021	1/2	1	Yes	NA	R (14MAY2021)	N/N
		GENRL	Injection site pain/ injection site pain#	3	14MAY2021	2/2	1	Yes	NA	R (15MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
C4591001 1039 10391290/ BNT162b2 (30 µg)	12/F/ WHITE	GENRL	Fatigue/ fatigue#	4	03JUN2021	1/2	1	Yes		NA	R (04JUN2021)	N/N	
		GENRL	Injection site pain/ injection site soreness#	4	04JUN2021	2/1	1	Yes		NA	R (04JUN2021)	N/N	
		NERV	Headache/ headache#	4	04JUN2021	2/2	1	Yes		NA	R (05JUN2021)	N/N	
	NERV	Presyncope/ Vasovagal episode#	2	13JUL2021	187/1	2	No	O		NA	R (13JUL2021)	N/N	
	C4591001 1039 10391292/ Placebo	13/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	14MAY2021	1/3	1	Yes		NA	R (16MAY2021)	N/N
				Injection site pain/ Injection site soreness#	3	14MAY2021	1/9	1	Yes		NA	R (22MAY2021)	N/N
			GASTR	Nausea/ Nausea#	4	04JUN2021	1/3	1	Yes		NA/TC	R (06JUN2021)	N/N
GENRL			Fatigue/ Fatigue#	4	04JUN2021	1/3	1	Yes		NA/TC	R (06JUN2021)	N/N	
C4591001 1039 10391294/ Placebo	13/M/ ASIAN		Injection site pain/ Injection arm soreness#	4	04JUN2021	1/7	1	Yes		NA/TC	R (10JUN2021)	N/N	
		GENRL	Injection site pain/ Injection site pain#	3	14MAY2021	1/3	1	Yes		NA	R (16MAY2021)	N/N	

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1039 10391296/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ Injection arm soreness#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/N
		GENRL	Injection site pain/ Injection site soreness#	3	14MAY2021	1/2	1	Yes		NA	R (15MAY2021)	N/N
		GASTR	Nausea/ nausea#	4	04JUN2021	1/3	1	Yes		NA	R (06JUN2021)	N/N
		GENRL	Axillary pain/ Left armpit soreness#	4	04JUN2021	1/3	1	Yes		NA	R (06JUN2021)	N/N
			Chills/ Chills#	4	04JUN2021	1/2	1	Yes		NA/TC	R (05JUN2021)	N/N
C4591001 1039 10391301/ Placebo	14/M/ WHITE	GENRL	Pyrexia/ Fever 102#	4	05JUN2021	2/1	2	Yes		NA/TC	R (05JUN2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	3	13MAY2021	1/6	1	Yes		NA	R (18MAY2021)	N/N
		NERV	Presyncope/ vasovagal episode#	2	13MAY2021	113/1	1	No	O	NA	R (13MAY2021)	N/N
		MUSC	Myalgia/ General muscle aches#	3	14MAY2021	2/3	1	Yes		NA	R (16MAY2021)	N/N
		NERV	Headache/ Headache#	3	14MAY2021	2/3	1	Yes		NA	R (16MAY2021)	N/N
	GENRL	Chills/ chills#	4	05JUN2021	2/2	1	Yes		NA	R (06JUN2021)	N/N	

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Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
C4591001 1039 10391303/ Placebo	13/M/ WHITE	NERV GENRL	Injection site pain/ injection site soreness#	4	05JUN2021	2/4	1	Yes		NA	R (08JUN2021)	N/N	
			Pain/ body aches#	4	05JUN2021	2/2	1	Yes		NA	R (06JUN2021)	N/N	
			Pyrexia/ fever#	4	05JUN2021	2/2	1	Yes		NA	R (06JUN2021)	N/N	
			Headache/ headache#	4	05JUN2021	2/2	1	Yes		NA	R (06JUN2021)	N/N	
			Chills/ chills#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/N	
	C4591001 1039 10391305/ Placebo	13/M/ WHITE	GENRL	Fatigue/ Fatigue#	3	15MAY2021	2/2	1	Yes		NA	R (16MAY2021)	N/N
	C4591001 1039 10391307/ Placebo	15/F/ WHITE	INJ&P	Muscle strain/ exacerbation of neck muscle strain#	3	14MAY2021	1/C	3	No	O	NA/TC	RG	N/N
			ENDO	Thyroid mass/ thyroid nodule#	3	01JUN2021	19/C	1	No	O	NA	N	N/N
			GENRL	Chills/ chills#	4	04JUN2021	1/3	2	Yes		NA/TC	R (06JUN2021)	N/N
				Injection site pain/ injection site soreness#	4	04JUN2021	1/4	2	Yes		NA	R (07JUN2021)	N/Y
			Pyrexia/ fever#	4	04JUN2021	1/3	1	Yes		NA/TC	R (06JUN2021)	N/N	

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C4591001 1039 10391309/ Placebo	14/M/ ASIAN	MUSC	Myalgia/ muscle aches#	4	04JUN2021	1/3	2	Yes		NA/TC	R (06JUN2021)	N/N
		NERV	Headache/ headache#	4	04JUN2021	1/3	2	Yes		NA/TC	R (06JUN2021)	N/N
		GASTR	Vomiting/ vomiting#	4	05JUN2021	2/2	1	Yes		NA	R (06JUN2021)	N/N
		METAB	Vitamin D deficiency/ Vitamin D deficiency#	4	11JUN2021	8/C	1	No	O	NA/TC	RG	N/N
		ENDO	Autoimmune thyroiditis/ Hashimoto's thyroiditis#	4	14JUN2021	11/C	1	No	O	NA	N	N/N
C4591001 1039 10391310/ Placebo	13/M/ WHITE	GENRL	Fatigue/ fatigue#	2	17MAY2021	111/2	1	Yes		NA	R (18MAY2021)	N/N
			Injection site pain/ injection site pain#	2	17MAY2021	111/2	1	Yes		NA	R (18MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	4	09JUN2021	2/4	1	Yes		NA	R (12JUN2021)	N/N
C4591001 1039 10391310/ Placebo	13/M/ WHITE	GENRL	Fatigue/ fatigue#	2	14MAY2021	109/2	1	Yes		NA	R (15MAY2021)	N/N
			Injection site bruising/ bruise at injection site#	3	14MAY2021	1/5	1	Yes		NA	R (18MAY2021)	N/N

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C4591001 1039 10391313/ Placebo	14/M/ WHITE	NERV	Headache/ headache#	2	14MAY2021	109/1	1	Yes		NA/TC	R (14MAY2021)	N/N
		GENRL	Injection site swelling/ swelling at injection site#	3	18MAY2021	5/14	1	Yes		NA	R (31MAY2021)	N/N
		GENRL	Injection site bruising/ bruising at injection site#	4	07JUN2021	1/8	1	Yes		NA	R (14JUN2021)	N/N
		GENRL	Fatigue/ fatigue#	4	08JUN2021	2/2	1	Yes		NA	R (09JUN2021)	N/N
		NERV	Headache/ headache#	4	08JUN2021	2/2	1	Yes		NA/TC	R (09JUN2021)	N/N
		GENRL	Pain/ General Body aches#	3	15MAY2021	2/1	2	Yes		NA/TC	R (15MAY2021)	N/N
		GENRL	Injection site pain/ Injection site soreness#	4	03JUN2021	1/3	1	Yes		NA	R (05JUN2021)	N/N
		GENRL	Pain/ General Body aches#	4	03JUN2021	1/3	2	Yes		NA/TC	R (05JUN2021)	N/N
C4591001 1039 10391314/ Placebo	14/F/ ASIAN	GENRL	Fatigue/ Fatigue#	4	04JUN2021	2/2	2	Yes		NA	R (05JUN2021)	N/N
		GENRL	Injection site pain/ Injection Site Pain#	3	17MAY2021	1/3	1	Yes		NA	R (19MAY2021)	N/N

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C4591001 1039 10391315/ BNT162b2 (30 µg)	14/M/ WHITE	NERV	Presyncope/ vasovagal episode#	2	22JUL2021	177/1	2	No	O	NA	R (22JUL2021)	N/N
C4591001 1039 10391317/ Placebo	12/M/ ASIAN	GASTR	Vomiting/ vomiting*		07JAN2021	1/1	1	No	O	NA	R (07JAN2021)	N/N
		NERV	Presyncope/ pre-syncope*		07JAN2021	1/1	1	No	O	NA	R (07JAN2021)	N/N
		GENRL	Chills/ chills#	3	15MAY2021	2/1	1	Yes		NA/TC	R (15MAY2021)	N/N
			Fatigue/ fatigue#	3	15MAY2021	2/1	1	Yes		NA	R (15MAY2021)	N/N
C4591001 1039 10391319/ Placebo	12/M/ WHITE	GENRL	Chills/ chills#	3	21MAY2021	2/2	2	Yes		NA/TC	R (22MAY2021)	N/N
			Injection site pain/ injection site pain#	3	21MAY2021	2/3	2	Yes		NA/TC	R (23MAY2021)	N/N
			Pyrexia/ fever - max temp 102.3#	3	21MAY2021	2/3	3	Yes		NA/TC	R (23MAY2021)	N/N
C4591001 1039 10391321/ Placebo	12/F/ WHITE	GENRL	Chills/ Chills#	3	17MAY2021	1/2	2	Yes		NA/TC	R (18MAY2021)	N/N
		GENRL	Injection site pain/ Injection arm soreness#	4	08JUN2021	1/2	1	Yes		NA/TC	R (09JUN2021)	N/N

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C4591001 1039 10391325/ Placebo	13/F/ ASIAN	GENRL	Chills/ Chills#	3	13MAY2021	1/3	2	Yes		NA/TC	R (15MAY2021)	N/N
			Fatigue/ fatigue#	3	13MAY2021	1/3	2	Yes		NA	R (15MAY2021)	N/N
		GENRL	Pyrexia/ Fever - up to 103.4#	3	13MAY2021	1/2	3	Yes		NA/TC	R (14MAY2021)	N/N
			Chills/ chills#	4	03JUN2021	1/3	1	Yes		NA/TC	R (05JUN2021)	N/N
		GENRL	Fatigue/ fatigue#	4	03JUN2021	1/2	1	Yes		NA	R (04JUN2021)	N/N
			Fatigue/ fatigue#	4	04JUN2021	2/4	2	Yes		NA	R (07JUN2021)	N/N
			Injection site bruising/ bruise at injection site#	4	04JUN2021	2/8	1	Yes		NA	R (11JUN2021)	N/N
			Pain/ generalized aches#	4	04JUN2021	2/2	1	Yes		NA/TC	R (05JUN2021)	N/N
C4591001 1039 10391326/ BNT162b2 (30 µg)	15/M/ ASIAN	PSYCH	Depression/ Depression Exacerbation	2	29MAR2021	57/5	3	No	O	NA/TC/TCN	R (02APR2021)	Y/N
C4591001 1039 10391327/ Placebo	15/M/ WHITE	GENRL	Fatigue/ Fatigue#	2	06JUN2021	126/3	1	Yes		NA	R (08JUN2021)	N/N
C4591001 1039	14/F/ WHITE	GENRL	Fatigue/ fatigue#	3	14MAY2021	1/4	1	Yes		NA	R (17MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
10391328/ Placebo			Injection site pain/ Injection site pain#	3	14MAY2021	1/4	1	Yes		NA/TC	R (17MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/N
			Injection site pain/ Injection arm soreness#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/N
C4591001 1039 10391329/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ Injection site soreness#	3	21MAY2021	2/3	1	Yes		NA	R (23MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	4	11JUN2021	2/3	1	Yes		NA	R (13JUN2021)	N/N
			Injection site pain/ injection arm soreness#	4	11JUN2021	2/3	1	Yes		NA	R (13JUN2021)	N/N
C4591001 1039 10391330/ BNT162b2 (30 µg)	15/M/ WHITE	GASTR	Abdominal pain upper/ stomach pain#	2	25JUN2021	144/1	1	No	O	NA	R (25JUN2021)	N/N
			Nausea/ nausea#	2	25JUN2021	144/1	1	No	O	NA	R (25JUN2021)	N/N
C4591001 1039 10391332/ BNT162b2 (30 µg)	13/F/ WHITE	PSYCH	Suicidal ideation/ Active Suicidal Ideation	2	12APR2021	70/10	4	No	O	NA/TC/TCN	R (21APR2021)	Y/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1039 10391333/ Placebo	15/M/ WHITE	GENRL	Fatigue/ fatigue#	4	12JUN2021	2/2	1	Yes		NA	R (13JUN2021)	N/N
C4591001 1039 10391337/ Placebo	15/M/ WHITE	GENRL	Chills/ chills#	3	14MAY2021	1/2	2	Yes		NA/TC	R (15MAY2021)	N/N
		GASTR	Vomiting/ vomit#	3	15MAY2021	2/1	1	Yes		NA/TC	R (15MAY2021)	N/N
		GENRL	Pyrexia/ Fever#	4	05JUN2021	2/2	1	Yes		NA/TC	R (06JUN2021)	N/N
C4591001 1039 10391339/ Placebo	12/F/ WHITE	GASTR	Nausea/ Nausea	1	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N
			Vomiting/ Vomiting	1	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N
C4591001 1044 10441265/ Placebo	14/M/ WHITE	INFEC	Sinusitis/ sinusitis#	4	16JUN2021	8/12	1	No	O	NA/TC	R (27JUN2021)	N/N
C4591001 1044 10441266/ BNT162b2 (30 µg)	14/F/ WHITE	SKIN	Acne/ Worsening of acne	2	07JAN2021	11/26	1	No	O	NA/TC	R (01FEB2021)	N/N
C4591001 1044 10441267/ Placebo	14/M/ WHITE	INJ&P	Fall/ Accidental fall	2	29APR2021	123/35	2	No	O	NA/TC	R (02JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1044 10441282/ Placebo	15/M/ WHITE	GENRL	Hand fracture/ thumb fracture	2	29APR2021	123/35	2	No	O	NA/TC	R (02JUN2021)	N/N
			Injection site pain/ injection site pain#	4	25MAR2021	2/1	1	Yes		NA	R (25MAR2021)	N/N
C4591001 1044 10441284/ Placebo	15/M/ WHITE	PSYCH	Depression/ depression	2	01FEB2021	35/C	1	No	O	NA/TC	RG	N/N
		PSYCH	Anxiety/ Anxiety	2	27APR2021	120/C	2	No	O	NA/TC	RG	N/N
C4591001 1044 10441285/ BNT162b2 (30 µg)	15/F/ WHITE	SURG	Wisdom teeth removal/ Wisdom teeth extraction	2	22JUN2021	175/1	2	No	O	NA	R (22JUN2021)	N/N
C4591001 1044 10441300/ BNT162b2 (30 µg)	15/M/ WHITE	GASTR	Abdominal pain upper/ Stomach pain#	2	31AUG2021	226/2	1	No	O	NA	R (01SEP2021)	N/N
C4591001 1044 10441303/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Injection site pain#	3	20APR2021	1/4	1	Yes		NA	R (23APR2021)	N/N
		MUSC	Myalgia/ generlized Muscle aches#	3	20APR2021	1/3	1	Yes		NA	R (22APR2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1044 10441309/ BNT162b2 (30 µg)	12/M/ WHITE	EYE	Eye pain/ Ocular Pain in Right Eye	2	12MAY2021	115/3	2	No	O	NA	R (14MAY2021)	N/N
C4591001 1044 10441320/ Placebo	15/M/ WHITE	GENRL	Chills/ chills#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/N
		NERV	Headache/ headache#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/N
C4591001 1044 10441328/ BNT162b2 (30 µg)	15/F/ WHITE	INFEC	Pilonidal cyst/ Pilonidal cyst	2	22APR2021	87/C	2	No	O	NA/TCN	RG	N/N
C4591001 1044 10441345/ Placebo	12/F/ WHITE	GASTR	Nausea/ nausea#	4	07JUN2021	1/2	1	Yes		NA/TC	R (08JUN2021)	N/N
			Vomiting/ vomitting#	4	07JUN2021	1/2	1	Yes		NA	R (08JUN2021)	N/N
		MUSC	Myalgia/ generalized myalgia#	4	07JUN2021	1/C	2	Yes		NA/TC	RG	N/N
		NERV	Dizziness/ dizziness#	4	07JUN2021	1/1	2	Yes		NA	R (07JUN2021)	N/N
C4591001 1044 10441354/ Placebo	13/F/ WHITE	PSYCH	Attention deficit hyperactivity disorder/	2	24APR2021	86/C	1	No	O	NA/TC	N	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1044 10441361/ BNT162b2 (30 µg)	15/M/ WHITE	SKIN	Worsening of ADHD	2	24APR2021	81/C	1	No	O	NA/TC	RG	N/N
			Dermatitis contact/ allergic contact dermatitis involving all extremities (contact with poison sumac)									
C4591001 1044 10441364/ BNT162b2 (30 µg)	15/F/ WHITE	PSYCH	Attention deficit hyperactivity disorder/ attention deficit hyperactivity disorder	2	29APR2021	86/	1	No	O	NA/TC	R	N/N
		CARD	Tachycardia/ Tachycardia#	2	19AUG2021	198/C	1	No	O	NA	RG	N/N
		NERV	Dizziness/ Lightheadedness#	2	19AUG2021	198/C	1	No	O	NA	RG	N/N
C4591001 1044 10441384/ Placebo	13/M/ WHITE	MUSC	Tendonitis/ Achilles tendinitis	2	08MAR2021	33/C	2	No	O	NA/TC	RG	N/N
		RESP	Nasal congestion/ nasal congestion	2	07MAY2021	93/C	1	No	O	NA/TC	RG	N/N
C4591001 1057 10571387/ Placebo	14/F/ WHITE	MUSC	Pain in extremity/ ARM SORENESS#	4	23JUN2021	1/2	1	Yes		NA	R (24JUN2021)	N/N
C4591001 1057	12/F/ WHITE	GENRL	Fatigue/ FATIGUE#	2	24MAY2021	141/1	1	Yes		NA	R (24MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Cause of Vax Rel <sup>c</sup> AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
10571389/ Placebo			Injection site pain/ LEFT ARM INJECTION SITE SORNESS#	2	24MAY2021	141/1	1	Yes	NA	R (24MAY2021)	N/N
C4591001 1057 10571407/ Placebo	15/M/ WHITE	GENRL	Fatigue/ FATIGUE#	4	02APR2021	1/3	1	Yes	NA	R (04APR2021)	N/N
			Injection site pain/ RIGHT ARM INJECTION SITE SORENESS#	4	02APR2021	1/3	1	Yes	NA	R (04APR2021)	N/N
C4591001 1057 10571408/ Placebo	14/M/ WHITE	GASTR	Nausea/ NAUSEA#	3	25MAY2021	1/2	1	Yes	NA	R (26MAY2021)	N/N
		NERV	Headache/ HEADACHE#	3	25MAY2021	1/2	1	Yes	NA	R (26MAY2021)	N/N
C4591001 1057 10571431/ Placebo	13/M/ WHITE	GENRL	Pain/ BODY ACHES#	4	21JUN2021	1/3	1	Yes	NA	R (23JUN2021)	N/N
C4591001 1057 10571432/ Placebo	12/F/ WHITE	GENRL	Fatigue/ FATIGUE#	4	01JUN2021	1/2	1	Yes	NA	R (02JUN2021)	N/N
			Injection site pain/ LEFT ARM	4	01JUN2021	1/2	1	Yes	NA	R (02JUN2021)	N/N

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Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1057 10571434/ Placebo	13/M/ MULTIPLE	GENRL	INJECTION SITE SORENESS# Injection site pain/ PAIN AT INJECTION SITE LEFT DELTOID#	4	29JUN2021	1/3	1	Yes		NA	R (01JUL2021)	N/N
		MUSC	Pain in extremity/ LEFT UPPER ARM PAIN#	4	29JUN2021	1/3	1	Yes		NA	R (01JUL2021)	N/N
C4591001 1057 10571441/ Placebo	13/M/ ASIAN	MUSC	Myalgia/ MUSCLE ACHES#	4	09JUN2021	1/3	1	Yes		NA	R (11JUN2021)	N/N
C4591001 1066 10661410/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ pain at injection site#	4	09JUN2021	2/3	1	Yes		NA	R (11JUN2021)	N/N
C4591001 1077 10771275/ Placebo	13/M/ WHITE	INJ&P	Fall/ FALL	2	07MAY2021	137/1	1	No	O	NA	R (07MAY2021)	N/N
			Ligament sprain/ RIGHT WRIST SPRAIN	2	07MAY2021	137/19	1	No	O	NA/TC	R (25MAY2021)	N/N
C4591001 1077 10771279/ BNT162b2 (30 µg)	13/M/ WHITE	INJ&P	Hand fracture/ RIGHT 5TH METACARPAL FRACTURE#	2	18MAY2021	135/30	1	No	O	NA	R (16JUN2021)	N/N
C4591001 1077	14/F/ WHITE	INJ&P	Concussion/ CONCUSSION	2	08APR2021	95/14	1	No	O	NA	R (21APR2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
10771280/ Placebo			Fall/ FALL	2	08APR2021	95/1	1	No	O	NA	R (08APR2021)	N/N
C4591001 1077 10771285/ Placebo	14/F/ WHITE	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	19MAY2021	2/3	1	Yes		NA/TC	R (21MAY2021)	N/N
C4591001 1077 10771295/ Placebo	15/M/ WHITE	INJ&P	Ligament rupture/ RIGHT KNEE ACL TEAR#	4	29MAR2021	13/29	2	No	O	NA/TCN	R (26APR2021)	N/N
			Meniscus injury/ RIGHT KNEE MENISCUS TEAR#	4	29MAR2021	13/29	2	No	O	NA	R (26APR2021)	N/N
			Sports injury/ FOOTBALL INJURY#	4	29MAR2021	13/1	2	No	O	NA	R (29MAR2021)	N/N
C4591001 1077 10771298/ Placebo	14/M/ WHITE	GENRL	Fatigue/ FATIGUE#	4	04JUN2021	1/2	1	Yes		NA	R (05JUN2021)	N/N
C4591001 1077 10771300/ BNT162b2 (30 µg)	15/F/ WHITE	REPRO	Amenorrhoea/ AMENORRHEA	1	12JAN2021	6/80	1	No	O	NA	R (01APR2021)	N/N
C4591001 1084	15/M/ WHITE	PSYCH	Obsessive- compulsive disorder/	2	09FEB2021	19/C	2	No	O	NA/TC	N	N/N

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10841560/ Placebo			Obsessive compulsive disorder									
C4591001 1084 10841569/ Placebo	14/F/ WHITE	NERV	Headache/ Headache	2	29JAN2021	8/15	1	No	O	NA	R (12FEB2021)	N/N
C4591001 1091 10911406/ BNT162b2 (30 µg)	14/M/ WHITE	PSYCH	Panic attack/ Panic attacks	2	25FEB2021	60/C	2	No	O	NA	N	N/N
		INJ&P	Upper limb fracture/ Broken right arm	2	25MAY2021	149/C	3	No	O	NA/TCN	RG	N/N
C4591001 1091 10911411/ Placebo	15/M/ WHITE	GASTR	Tooth impacted/ Tooth impaction#	4	15JUL2021	22/1	2	No	O	NA	R (15JUL2021)	N/N
C4591001 1091 10911414/ BNT162b2 (30 µg)	14/M/ WHITE	GENRL	Injection site pain/ Injection site pain#	2	26MAY2021	2/2	1	Yes		NA	R (27MAY2021)	N/N
C4591001 1091 10911417/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ Injection site pain left arm#	3	18MAY2021	1/1	1	Yes		NA	R (18MAY2021)	N/N
			Pyrexia/ Fever#	3	18MAY2021	1/1	1	Yes		NA/TC	R (18MAY2021)	N/N
C4591001 1091	14/F/ BLACK OR	GASTR	Diarrhoea/ Diarrhea#	4	22JUL2021	2/2	1	Yes		NA	R (23JUL2021)	N/N

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10911423/ Placebo	AFRICAN AMERICAN		Vomiting/ Vomitting#	4	22JUL2021	2/2	1	Yes		NA	R (23JUL2021)	N/N
		MUSC	Myalgia/ Myalgia#	4	22JUL2021	2/2	1	Yes		NA	RS (23JUL2021)	N/N
		NERV	Headache/ Headache#	4	22JUL2021	2/2	1	Yes		NA	R (23JUL2021)	N/N
C4591001 1091 10911447/ BNT162b2 (30 µg)	15/M/ WHITE	INFEC	Appendicitis/ Appendicitis#	2	09JUL2021	177/2	2	No	O	NA/TCN	R (10JUL2021)	Y/N
C4591001 1091 10911463/ Placebo	15/M/ WHITE	GASTR	Tooth impacted/ Wisdom teeth impaction	2	27APR2021	91/11	1	No	O	NA/TCN	R (07MAY2021)	N/N
C4591001 1123 11231440/ BNT162b2 (30 µg)	13/M/ WHITE	INFEC	Otitis media/ Left otitis media#	2	13AUG2021	229/9	2	No	O	NA/TC	R (21AUG2021)	N/N
C4591001 1123 11231442/ Placebo	12/M/ WHITE	NERV	Headache/ headache	1	16DEC2020	8/2	1	No	O	NA/TC	R (17DEC2020)	N/N
		PSYCH	Depression/ worsening of depression	2	MAR2021	57/	1	No	O	NA/TC	R (04JUN2021)	N/N

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C4591001 1123 11231473/ Placebo	15/F/ WHITE	INJ&P	Hand fracture/ avulsion fracture right middle finger	2	11APR2021	90/C	2	No	O	NA/TC/TCN	RG	N/N
C4591001 1123 11231489/ BNT162b2 (30 µg)	13/M/ WHITE	INJ&P	Meniscus injury/ Torn medial and lateral left knee menisci	2	MAR2021	50/C	1	No	O	NA/TC	RG	N/N
C4591001 1123 11231507/ BNT162b2 (30 µg)	14/F/ WHITE	PSYCH	Attention deficit hyperactivity disorder/ WORSENING Attention Deficit Hyper Activity Disorder	2	01MAR2021	43/C	1	No	O	NA/TC	N	N/N
C4591001 1124 11241245/ BNT162b2 (30 µg)	14/F/ WHITE	PSYCH	Anxiety/ Anxiety	2	MAR2021	55/C	2	No	O	NA/TC	RG	N/N
			Depression/ Depression	2	MAR2021	55/C	2	No	O	NA/TC	RG	N/N
C4591001 1126 11261233/ Placebo	14/M/ WHITE	GENRL	Fatigue/ Fatigue#	3	19MAY2021	1/2	1	Yes		NA	R (20MAY2021)	N/N
			Injection site pain/ Left Upper Arm Injection Site Pain#	3	19MAY2021	1/3	2	Yes		NA	R (21MAY2021)	N/N
		MUSC	Myalgia/ Muscle Aches#	3	20MAY2021	2/2	2	Yes		NA	R (21MAY2021)	N/N

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C4591001 1126 11261235/ Placebo	12/F/ WHITE	GENRL	Fatigue/ Fatigue#	4	09JUN2021	1/4	2	Yes		NA	R (12JUN2021)	N/N
		SKIN	Photosensitivity reaction/ Phyto photodermatitis, bilateral hands#	3	23MAY2021	6/4	2	No	O	NA/TC/TCN	R (26MAY2021)	N/N
		GENRL	Pain/ Generalized body aches#	4	09JUN2021	2/1	1	Yes		NA/TC	R (09JUN2021)	N/N
C4591001 1126 11261239/ Placebo	15/F/ WHITE		Pyrexia/ Fever#	4	09JUN2021	2/1	1	Yes		NA/TC	R (09JUN2021)	N/N
		GENRL	Injection site pain/ Left arm injection site pain#	3	17MAY2021	1/3	2	Yes		NA	R (19MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	07JUN2021	1/2	2	Yes		NA	R (08JUN2021)	N/N
			Injection site pain/ Pain, injection site#	4	07JUN2021	1/2	2	Yes		NA	R (08JUN2021)	N/N
C4591001 1126 11261240/ Placebo	15/M/ WHITE		Pain/ Generalized body aches#	4	07JUN2021	1/2	2	Yes		NA	R (08JUN2021)	N/N
			Pyrexia/ Fever#	4	07JUN2021	1/2	2	Yes		NA/TC	R (08JUN2021)	N/N
		GENRL	Injection site pain/ Pain, injection site#	3	21MAY2021	1/2	2	Yes		NA	R (22MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	10JUN2021	1/2	1	Yes		NA	R (11JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261250/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ Pain, injection site#	4	10JUN2021	1/2	1	Yes		NA	R (11JUN2021)	N/N
			Pain/ Generalized body aches#	4	10JUN2021	1/2	1	Yes		NA	R (11JUN2021)	N/N
		GENRL	Injection site pain/ Pain, Injection Site#	3	19MAY2021	1/2	1	Yes		NA	R (20MAY2021)	N/N
			Fatigue/ Fatigue#	4	15JUN2021	1/2	1	Yes		NA	R (16JUN2021)	N/N
C4591001 1126 11261253/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ Pain, injection site#	4	15JUN2021	1/2	1	Yes		NA	R (16JUN2021)	N/N
			Chills/ Chills#	3	17MAY2021	1/1	2	Yes		NA	R (17MAY2021)	N/N
		MUSC  GENRL GENRL	Injection site pain/ Left arm injection site pain#	3	17MAY2021	1/3	1	Yes		NA/TC	R (19MAY2021)	N/N
			Myalgia/ Muscle aches#	3	17MAY2021	1/3	2	Yes		NA/TC	R (19MAY2021)	N/N
			Fatigue/ Fatigue#	3	18MAY2021	2/2	2	Yes		NA	R (19MAY2021)	N/N
			Fatigue/ Fatigue#	4	08JUN2021	1/2	1	Yes		NA	R (09JUN2021)	N/N
C4591001 1126 11261254/ Placebo	15/M/ WHITE	GENRL	Chills/ Chills#	3	23JUN2021	2/1	1	Yes		NA	R (23JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261262/ Placebo	15/F/ WHITE		Injection site pain/ Injection site pain#	3	23JUN2021	2/3	1	Yes		NA	R (25JUN2021)	N/N
			Malaise/ Malaise#	3	23JUN2021	2/1	1	Yes		NA	R (23JUN2021)	N/N
		NERV	Headache/ Headache#	3	23JUN2021	2/1	1	Yes		NA	R (23JUN2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	12JUL2021	1/2	1	Yes		NA	R (13JUL2021)	N/N
		NERV	Headache/ Headache#	4	12JUL2021	1/2	1	Yes		NA	R (13JUL2021)	N/N
		GENRL	Malaise/ Malaise#	4	03MAR2021	1/2	2	Yes		NA	R (04MAR2021)	N/N
		NERV	Headache/ Headache#	4	03MAR2021	1/2	1	Yes		NA	R (04MAR2021)	N/N
C4591001 1126 11261265/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Injection site pain#	4	04MAR2021	2/3	1	Yes		NA	R (06MAR2021)	N/N
		GENRL	Injection site pain/ Pain, injection site#	3	20MAY2021	2/4	1	Yes		NA	R (23MAY2021)	N/N
C4591001 1126 11261266/ Placebo	12/F/ WHITE	GENRL	Injection site pain/ Pain, injection site#	4	14JUN2021	1/2	1	Yes		NA	R (15JUN2021)	N/N
		GENRL	Injection site pain/ Pain, Injection site#	3	19MAY2021	1/2	1	Yes		NA	R (20MAY2021)	N/N
		GENRL	Injection site pain/ Pain, injection site#	4	15JUN2021	2/1	1	Yes		NA	R (15JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261267/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ Left upper arm injection site pain#	3	21MAY2021	1/3	2	Yes		NA/TC	R (23MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	22MAY2021	2/1	2	Yes		NA	R (22MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	11JUN2021	1/3	2	Yes		NA	R (13JUN2021)	N/N
			Injection site pain/ PAIN, INJECTION SITE#	4	11JUN2021	1/3	2	Yes		NA/TC	R (13JUN2021)	N/N
			Pain/ GENERALIZED BODY ACHES#	4	11JUN2021	1/3	2	Yes		NA/TC	R (13JUN2021)	N/N
			Pyrexia/ Fever#	4	11JUN2021	1/2	2	Yes		NA/TC	R (12JUN2021)	N/N
C4591001 1126 11261270/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Left upper arm injection site pain#	2	20MAY2021	135/2	1	Yes		NA	R (21MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	11JUN2021	2/2	1	Yes		NA	R (12JUN2021)	N/N
C4591001 1126 11261271/ BNT162b2 (30 µg)	15/M/ WHITE	INV	SARS-CoV-2 antibody test positive/ SARS-COV-2 IGG, QL, IA - Positive	2	21JAN2021	16/C	1	Yes		NA	N	N/N
C4591001 1126 11261274/ Placebo	15/F/ WHITE	GENRL	Injection site pain/ Left upper arm injection site pain#	3	20MAY2021	1/3	2	Yes		NA/TC	R (22MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261276/ Placebo	15/M/ WHITE	NERV	Headache/ Headache#	3	21MAY2021	2/1	2	Yes		NA/TC	R (21MAY2021)	N/N
		GENRL	Injection site pain/ Pain, injection site#	4	11JUN2021	2/3	1	Yes		NA	R (13JUN2021)	N/N
		GENRL	Malaise/ Malaise#	4	03MAR2021	1/2	1	Yes		NA	R (04MAR2021)	N/N
		NERV	Headache/ Headache#	4	03MAR2021	1/2	1	Yes		NA	R (04MAR2021)	N/N
C4591001 1126 11261279/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Left upper arm injection site pain#	3	20MAY2021	1/4	1	Yes		NA/TC	R (23MAY2021)	N/N
		GENRL	Chills/ Chills#	3	21MAY2021	2/1	2	Yes		NA	R (21MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	11JUN2021	1/3	2	Yes		NA	R (13JUN2021)	N/N
			Pain/ Body aches#	4	11JUN2021	1/3	2	Yes		NA	R (13JUN2021)	N/N
C4591001 1126 11261280/ Placebo	12/M/ WHITE		Pyrexia/ Fever#	4	11JUN2021	1/1	1	Yes		NA	R (11JUN2021)	N/N
		GENRL	Injection site pain/ Left upper arm injection site pain#	3	20MAY2021	1/3	2	Yes		NA/TC	R (22MAY2021)	N/N
		MUSC	Myalgia/ Muscle aches#	3	21MAY2021	2/1	2	Yes		NA/TC	R (21MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	11JUN2021	1/3	2	Yes		NA	R (13JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261283/ Placebo	13/F/ ASIAN	GENRL	Pain/ Body aches#	4	11JUN2021	1/3	2	Yes		NA	R (13JUN2021)	N/N
			Pyrexia/ Fever#	4	11JUN2021	1/1	1	Yes		NA	R (11JUN2021)	N/N
			Fatigue/ Fatigue#	3	18MAY2021	2/2	2	Yes		NA	R (19MAY2021)	N/N
			Injection site pain/ Right Arm Injection Site Pain#	3	18MAY2021	2/2	2	Yes		NA/TC	R (19MAY2021)	N/N
			NERV Headache/ Headache#	3	18MAY2021	2/1	2	Yes		NA/TC	R (18MAY2021)	N/N
C4591001 1126 11261284/ Placebo	13/F/ ASIAN	GENRL	Fatigue/ Fatigue#	4	10JUN2021	2/1	1	Yes		NA	R (10JUN2021)	N/N
		GENRL	Injection site pain/ Pain, injection site	2	07JAN2021	2/153	2	Yes		NA	R (08JUN2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	18MAY2021	2/3	1	Yes		NA	R (20MAY2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	3	18MAY2021	2/3	1	Yes		NA	R (20MAY2021)	N/N
		GENRL	Pyrexia/ Fever, 101F#	3	18MAY2021	2/1	2	Yes		NA/TC	R (18MAY2021)	N/N
C4591001 1126 11261287/ Placebo	15/M/ WHITE	GENRL	Injection site hypoesthesia/ Injection Site numbness#	3	20MAY2021	1/2	1	Yes		NA	R (21MAY2021)	N/N
		GENRL	Injection site pain/ Pain, injection site#	4	11JUN2021	2/1	2	Yes		NA	R (11JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261289/ Placebo	14/F/ WHITE	GENRL	Injection site swelling/ Swelling, injection site#	4	11JUN2021	2/1	2	Yes		NA	R (11JUN2021)	N/N
			Fatigue/ Fatigue#	3	17MAY2021	1/2	2	Yes		NA	R (18MAY2021)	N/N
			Injection site pain/ Pain, Injection Site#	3	17MAY2021	1/3	2	Yes		NA	R (19MAY2021)	N/N
C4591001 1126 11261290/ Placebo	12/M/ NOT REPORTED	GENRL	Fatigue/ Fatigue#	3	18MAY2021	1/4	2	Yes		NA/TC	R (21MAY2021)	N/N
			Chills/ Chills#	3	19MAY2021	2/3	1	Yes		NA/TC	R (21MAY2021)	N/N
			Injection site pain/ Injection Site Pain#	3	19MAY2021	2/3	1	Yes		NA/TC	R (21MAY2021)	N/N
C4591001 1126 11261292/ Placebo	12/F/ ASIAN	GENRL	Fatigue/ Fatigue#	4	09JUN2021	1/2	1	Yes		NA	R (10JUN2021)	N/N
			Injection site pain/ Pain, injection site#	4	09JUN2021	1/4	1	Yes		NA	R (12JUN2021)	N/N
			Chills/ Chills#	3	17MAY2021	1/1	2	Yes		NA/TC	R (17MAY2021)	N/N
			Injection site pain/ Left arm injection site pain#	3	17MAY2021	1/3	2	Yes		NA/TC	R (19MAY2021)	N/N
			Fatigue/ Fatigue#	3	18MAY2021	2/2	2	Yes		NA	R (19MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261294/ Placebo	13/F/ WHITE	MUSC	Myalgia/ Muscle aches#	3	18MAY2021	2/2	2	Yes		NA/TC	R (19MAY2021)	N/N
		NERV	Headache/ Headache#	3	18MAY2021	2/2	1	Yes		NA/TC	R (19MAY2021)	N/N
		GENRL	Chills/ Chills#	4	07JUN2021	1/2	2	Yes		NA	R (08JUN2021)	N/N
			Pain/ Generalized body aches#	4	07JUN2021	1/2	2	Yes		NA	R (08JUN2021)	N/N
			Pyrexia/ Fever#	4	07JUN2021	1/2	1	Yes		NA	R (08JUN2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	08JUN2021	2/2	2	Yes		NA	R (09JUN2021)	N/N
		NERV	Headache/ Headache#	4	08JUN2021	2/2	1	Yes		NA	R (09JUN2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	17JUL2021	2/2	2	Yes		NA	R (18JUL2021)	N/N
			Injection site pain/ Injection Site Pain#	3	17JUL2021	2/3	1	Yes		NA	R (19JUL2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	4	07AUG2021	2/2	1	Yes		NA	R (08AUG2021)	N/N
C4591001 1126 11261296/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Pain injection site#	3	08APR2021	2/2	1	Yes		NA	R (09APR2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	4	27APR2021	2/2	1	Yes		NA	R (28APR2021)	N/N

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Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261297/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ Left Upper Arm Injection Site Pain#	3	19MAY2021	1/3	2	Yes		NA	R (21MAY2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	4	09JUN2021	1/2	1	Yes		NA	R (10JUN2021)	N/N
C4591001 1126 11261300/ Placebo	13/M/ ASIAN	GENRL	Injection site pain/ Left upper arm injection site pain#	3	19MAY2021	1/2	2	Yes		NA/TC	R (20MAY2021)	N/N
		GENRL	Pain/ Generalized body aches#	4	12JUN2021	2/2	1	Yes		NA/TC	R (13JUN2021)	N/N
C4591001 1126 11261302/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Left upper arm injection site pain#	3	21MAY2021	1/2	1	Yes		NA	R (22MAY2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	4	11JUN2021	1/3	1	Yes		NA	R (13JUN2021)	N/N
C4591001 1126 11261305/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Injection site pain#	4	17MAR2021	1/2	1	Yes		NA	R (18MAR2021)	N/N
C4591001 1126 11261306/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ Left upper arm injection site pain#	3	18MAY2021	1/3	2	Yes		NA	R (20MAY2021)	N/N
C4591001 1126 11261308/ Placebo	12/M/ WHITE	GENRL	Pyrexia/ Fever 101`F#	3	19JUN2021	2/1	2	Yes		NA/TC	R (19JUN2021)	N/N

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Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261311/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ Injection Site Pain#	4	10JUL2021	2/3	1	Yes		NA	R (12JUL2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	3	02JUN2021	1/2	1	Yes		NA	R (03JUN2021)	N/N
C4591001 1126 11261312/ Placebo	14/F/ WHITE	GENRL	Malaise/ Malaise#	4	22JUN2021	2/2	1	Yes		NA	R (23JUN2021)	N/N
		GENRL	Injection site pain/ Left upper arm injection site pain#	3	18MAY2021	1/3	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1126 11261314/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ Pain, injection site#	4	09JUN2021	1/3	2	Yes		NA/TC	R (11JUN2021)	N/N
			Pain/ Generalized body aches#	4	09JUN2021	1/3	2	Yes		NA/TC	R (11JUN2021)	N/N
			Pyrexia/ Fever#	4	09JUN2021	1/3	2	Yes		NA/TC	R (11JUN2021)	N/N
			Fatigue/ Fatigue#	3	19MAY2021	1/1	2	Yes		NA	R (19MAY2021)	N/N
C4591001 1126	12/F/ WHITE		Injection site pain/ Pain, injection site#	3	19MAY2021	1/3	2	Yes		NA	R (21MAY2021)	N/N
		GENRL	Pyrexia/ Fever#	3	20MAY2021	2/1	2	Yes		NA/TC	R (20MAY2021)	N/N
		NERV	Headache/ Headache#	3	20MAY2021	2/1	2	Yes		NA	R (20MAY2021)	N/N
C4591001 1126		GENRL	Injection site pain/ Injection Site Pain#	3	17MAY2021	1/3	1	Yes		NA	R (19MAY2021)	N/N

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Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Cause of Vaccine AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
11261317/ Placebo		GENRL	Injection site pain/ Injection site pain#	4	09JUN2021	1/3	1	Yes	NA	R (11JUN2021)	N/N
		GENRL	Malaise/ Malaise#	4	10JUN2021	2/3	1	Yes	NA	R (12JUN2021)	N/N
C4591001 1126 11261318/ Placebo	12/F/ WHITE	GENRL	Chills/ Chills#	3	05AUG2021	1/3	1	Yes	NA	R (07AUG2021)	N/N
			Injection site pain/ Injection site pain#	3	05AUG2021	1/3	1	Yes	NA	R (07AUG2021)	N/N
C4591001 1126 11261320/ Placebo	12/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	18MAY2021	1/2	1	Yes	NA	R (19MAY2021)	N/N
			Injection site pain/ Pain, injection site#	3	18MAY2021	1/2	1	Yes	NA	R (19MAY2021)	N/N
		GENRL	Injection site pain/ Pain, injection site#	4	09JUN2021	2/1	1	Yes	NA	R (09JUN2021)	N/N
C4591001 1126 11261322/ Placebo	13/M/ ASIAN	GENRL	Injection site pain/ Pain, Injection site#	3	25MAY2021	2/4	2	Yes	NA	R (28MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	14JUN2021	1/2	1	Yes	NA	R (15JUN2021)	N/N
			Pain/ Generalized body aches#	4	14JUN2021	1/2	1	Yes	NA	R (15JUN2021)	N/N

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Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1126 11261325/ Placebo	12/F/ WHITE	NERV	Headache/ Headache#	4	14JUN2021	1/2	1	Yes		NA	R (15JUN2021)	N/N
		GENRL	Chills/ Chills#	3	18MAY2021	1/1	2	Yes		NA	R (18MAY2021)	N/N
			Injection site pain/ Left upper arm injection site pain#	3	18MAY2021	1/3	1	Yes		NA/TC	R (20MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	19MAY2021	2/1	1	Yes		NA	R (19MAY2021)	N/N
		NERV	Headache/ Headache#	3	19MAY2021	2/1	1	Yes		NA/TC	R (19MAY2021)	N/N
C4591001 1131 11311285/ Placebo	14/F/ WHITE	GENRL	Chills/ Body Chills#	4	09JUN2021	2/1	1	Yes		NA	R (09JUN2021)	N/N
		GENRL	Injection site pain/ injection site pain#	3	15JUN2021	2/2	1	Yes		NA	R (16JUN2021)	N/N
			Pain/ body aches#	3	15JUN2021	2/2	1	Yes		NA	R (16JUN2021)	N/N
C4591001 1131 11311287/ Placebo	12/F/ BLACK OR AFRICAN AMERICAN	NERV	Headache/ headache#	3	15JUN2021	2/2	1	Yes		NA	R (16JUN2021)	N/N
		INFEC	Ear infection/ ear infection#	4	01JUL2021	16/11	1	No	O	NA	R (11JUL2021)	N/N
C4591001 1131 11311288/ Placebo	12/F/ BLACK OR AFRICAN AMERICAN	GASTR	Vomiting/ vomiting#	4	17JUN2021	2/1	1	No	O	NA	R (17JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1131 11311293/ Placebo	12/F/ WHITE	GENRL	Chest pain/ chest pain#	4	17JUN2021	2/2	2	No	O	NA	R (18JUN2021)	N/N
			Pyrexia/ fever#	4	17JUN2021	2/1	1	No	O	NA	R (17JUN2021)	N/N
		INFEC	Pharyngitis streptococcal/ strep throat#	4	17JUN2021	2/3	1	No	O	NA	R (19JUN2021)	N/N
		MUSC	Myalgia/ general myalgia#	4	17JUN2021	2/2	1	No	O	NA	R (18JUN2021)	N/N
		NERV	Headache/ headache#	4	17JUN2021	2/3	1	No	O	NA	R (19JUN2021)	N/N
		RESP	Cough/ cough#	4	17JUN2021	2/1	1	No	O	NA	R (17JUN2021)	N/N
			Nasal congestion/ nasal congestion#	4	17JUN2021	2/4	1	No	O	NA	R (20JUN2021)	N/N
C4591001 1131 11311299/ Placebo	15/M/ WHITE	GASTR	Abdominal pain upper/ Stomach ache#	4	03AUG2021	1/2	2	Yes		NA/TC	R (04AUG2021)	N/N
		GENRL	Pyrexia/ Low grade temperature elevation#	4	03AUG2021	1/1	1	Yes		NA/TC	R (03AUG2021)	N/N
		GENRL	Injection site pain/ injection site pain#	3	20MAY2021	1/3	1	Yes		NA	R (22MAY2021)	N/N
	GASTR	Nausea/ nausea#	4	11JUN2021	2/1	1	Yes		NA	R (11JUN2021)	N/N	
	GENRL	Pyrexia/ febrile#	4	11JUN2021	2/1	2	Yes		NA/TC	R (11JUN2021)	N/N	

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1131 11311300/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ injection site pain#	3	20MAY2021	1/4	2	Yes		NA/TC	R (23MAY2021)	N/N
		INJ&P	Sunburn/ sun burn(face and shoulders)#	3	07JUN2021	19/C	3	No	O	NA/TC	RG	N/N
		GENRL	Chills/ chills#	4	10JUN2021	1/2	2	Yes		NA/TC	R (11JUN2021)	N/N
			Pyrexia/ fever#	4	10JUN2021	1/2	2	Yes		NA/TC	R (11JUN2021)	N/N
C4591001 1139 11391171/ Placebo	15/M/ WHITE	INJ&P	Skin laceration/ laceration of forehead	2	10MAR2021	65/7	2	No	O	NA	R (16MAR2021)	N/N
C4591001 1139 11391179/ BNT162b2 (30 µg)	15/M/ WHITE	NERV	Syncope/ syncope#	2	12JUL2021	186/1	2	No	O	NA	R (12JUL2021)	N/N
C4591001 1139 11391210/ Placebo	14/M/ WHITE	INJ&P	Concussion/ Concussion#	3	08JUN2021	14/18	3	No	O	NA/TC	R (25JUN2021)	N/N
			Hyphaema/ traumatic hyphema of left eye#	3	08JUN2021	14/18	2	No	O	NA/TC	R (25JUN2021)	N/N
C4591001 1139 11391217/ Placebo	13/M/ WHITE	INFEC	Otitis externa/ Otitis Externa#	4	29JUN2021	22/8	1	No	O	NA/TC	R (06JUL2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1140 11401330/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ pain at injection site#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
		GENRL	Fatigue/ fatigue#	4	09JUN2021	2/2	1	Yes		NA	R (10JUN2021)	N/N
			Pyrexia/ fever#	4	09JUN2021	2/2	1	Yes		NA	R (10JUN2021)	N/N
C4591001 1140 11401335/ Placebo	14/F/ WHITE	GENRL	Pyrexia/ fever#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
C4591001 1140 11401338/ Placebo	15/F/ WHITE	GENRL	Injection site pain/ Pain at the injection site#	3	17MAY2021	1/3	1	Yes		NA	RS (19MAY2021)	N/N
		MUSC	Myalgia/ Mayalgias#	3	18MAY2021	2/2	1	Yes		NA	R (19MAY2021)	N/N
		NERV	Headache/ Headache#	3	18MAY2021	2/2	1	Yes		NA	R (19MAY2021)	N/N
		GENRL	Injection site pain/ pain at injection site#	4	07JUN2021	1/C	1	Yes		NA	RG	N/Y
C4591001 1140 11401353/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ Pain at the injection site#	3	21MAY2021	1/3	1	Yes		NA	R (23MAY2021)	N/N
		GENRL	Pyrexia/ Fever#	3	22MAY2021	2/2	1	Yes		NA	R (23MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1140 11401354/ BNT162b2 (30 µg)	15/F/ WHITE	CONG	Syringomyelia/ Thoracic spinal syrinx#	2	JUN2021	140/C	3	No	O	NA/TC/TCN	N	Y/N
C4591001 1140 11401356/ Placebo	14/F/ MULTIPLE	GENRL	Fatigue/ Fatigue#	3	20MAY2021	1/2	1	Yes		NA	R (21MAY2021)	N/N
			Injection site pain/ Pain at injection site#	3	20MAY2021	1/2	1	Yes		NA	R (21MAY2021)	N/N
			Pyrexia/ Fever#	3	20MAY2021	1/3	1	Yes		NA	R (22MAY2021)	N/N
		NERV	Headache/ Headache#	3	20MAY2021	1/2	1	Yes		NA	R (21MAY2021)	N/N
C4591001 1140 11401362/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ pain at injection site#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
C4591001 1140 11401364/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	22MAY2021	2/3	1	Yes		NA	R (24MAY2021)	N/N
C4591001 1140 11401365/ BNT162b2 (30 µg)	15/M/ WHITE	PSYCH	Suicidal ideation/ Suicidal Ideation	2	04APR2021	76/2	3	No	O	NA/TC/TCN	R (05APR2021)	Y/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1140 11401366/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	22MAY2021	2/3	1	Yes		NA	R (24MAY2021)	N/N
C4591001 1140 11401372/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ pain at injection site#	3	18MAY2021	1/C	1	Yes		NA	RG	N/Y
C4591001 1140 11401374/ Placebo	14/F/ WHITE	GENRL	Pain/ body aches#	3	28MAY2021	1/3	1	Yes		NA/TC	R (30MAY2021)	N/N
		GASTR	Vomiting/ vomiting#	3	30MAY2021	3/1	1	Yes		NA	R (30MAY2021)	N/N
C4591001 1140 11401383/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	21MAY2021	1/3	1	Yes		NA	R (23MAY2021)	N/N
C4591001 1140 11401384/ Placebo	14/F/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	18MAY2021	2/3	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1140 11401385/ BNT162b2 (30 µg)	12/F/ WHITE	IMMUN	Seasonal allergy/ Seasonal Allergies	2	MAR2021	34/C	2	No	O	NA	RG	N/N
C4591001 1140 11401387/ Placebo	12/M/ WHITE	INJ&P	Contusion/ Left arm contusion#	2	16MAY2021	109/8	1	No	O	NA/TCN	R (23MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1140 11401388/ Placebo	15/M/ WHITE	GENRL	Fatigue/ fatigue#	3	19MAY2021	1/2	1	Yes		NA	R (20MAY2021)	N/N
			Injection site pain/ pain at injection site#	3	19MAY2021	1/3	1	Yes		NA	R (21MAY2021)	N/N
		NERV	Headache/ headache#	3	20MAY2021	2/1	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1140 11401389/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ pain at injection site#	3	19MAY2021	1/3	1	Yes		NA	R (21MAY2021)	N/N
C4591001 1140 11401392/ Placebo	15/M/ WHITE	GENRL	Fatigue/ Fatigue#	3	19MAY2021	1/2	1	Yes		NA	R (20MAY2021)	N/N
			Injection site pain/ Pain at injection site#	3	19MAY2021	1/1	1	Yes		NA	R (19MAY2021)	N/N
C4591001 1140 11401395/ Placebo	12/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	20MAY2021	1/1	1	Yes		NA	R (20MAY2021)	N/N
		NERV	Headache/ Headache#	3	20MAY2021	1/1	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1142 11421326/ Placebo	12/F/ WHITE	GENRL	Injection site erythema/ injection site redness#	3	25MAY2021	2/6	1	Yes		NA	R (30MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Injection site pain/ injection site pain#	3	25MAY2021	2/6	1	Yes		NA	R (30MAY2021)	N/N
			Injection site swelling/ injection site swelling#	3	25MAY2021	2/6	1	Yes		NA	R (30MAY2021)	N/N
C4591001 1142 11421335/ Placebo	13/F/ WHITE	GENRL	Fatigue/ fatigue#	3	30JUL2021	1/2	2	Yes		NA	R (31JUL2021)	N/N
			Injection site pain/ injection site pain#	3	30JUL2021	1/2	2	Yes		NA	R (31JUL2021)	N/N
			Malaise/ malaise#	3	30JUL2021	1/2	2	Yes		NA	R (31JUL2021)	N/N
C4591001 1142 11421355/ Placebo	12/M/ MULTIPLE	GENRL	Injection site pain/ injection site pain#	3	27JUL2021	1/2	2	Yes		NA	R (28JUL2021)	N/N
C4591001 1142 11421356/ Placebo	14/F/ BLACK OR AFRICAN AMERICAN	GENRL	Injection site pain/ injection site pain#	3	27JUL2021	1/2	2	Yes		NA	R (28JUL2021)	N/N
C4591001 1142 11421393/ Placebo	13/M/ WHITE	GENRL	Injection site pain/ injection site pain#	3	31AUG2021	1/3	1	Yes		NA	R (02SEP2021)	N/N
C4591001 1147 11471302/ BNT162b2 (30 µg)	15/F/ WHITE	RESP	Nasal congestion/ Nasal congestion	2	19MAR2021	70/3	1	No	O	NA/TC	R (21MAR2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1147 11471307/ Placebo	13/M/ WHITE	GENRL	Rhinorrhoea/ Runny nose	2	19MAR2021	70/3	1	No	O	NA/TC	R (21MAR2021)	N/N
			Sneezing/ Sneezing	2	19MAR2021	70/3	1	No	O	NA/TC	R (21MAR2021)	N/N
			Injection site erythema/ Redness at injection site#	3	13MAY2021	1/4	1	Yes		NA	R (16MAY2021)	N/N
			Injection site pain/ Pain at injection site#	3	13MAY2021	1/4	1	Yes		NA	R (16MAY2021)	N/N
			NERV Headache/ Headache#	3	13MAY2021	1/4	1	Yes		NA	R (16MAY2021)	N/N
C4591001 1147 11471320/ BNT162b2 (30 µg)	15/F/ WHITE	PSYCH	Anxiety/ Anxiety#	2	MAY2021	95/C	2	No	O	NA/TC	N	N/N
C4591001 1147 11471321/ Placebo	15/M/ BLACK OR AFRICAN AMERICAN	METAB	Glucose tolerance impaired/ pre-diabetes#	4	02JUL2021	26/C	1	No	O	NA	N	N/N
C4591001 1147 11471336/ Placebo	15/F/ WHITE	GASTR	Vitamin D deficiency/ vitamin D deficiency#	4	02JUL2021	26/C	1	No	O	NA/TC	N	N/N
			Nausea/ Nausea	2	11APR2021	75/C	1	No	O	NA	N	N/N

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Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1147 11471345/ Placebo	15/M/ WHITE	MUSC	Myalgia/ Generalized muscle pain#	3	20MAY2021	2/2	1	Yes		NA	R (21MAY2021)	N/N
C4591001 1150 11501120/ Placebo	15/M/ WHITE	MUSC	Tendonitis/ Tendonitis	2	MAR2021	116/	1	No	O	NA	R	N/N
		GENRL	Injection site pain/ Pain at injection site#	3	21MAY2021	2/1	1	Yes		NA	R (21MAY2021)	N/N
C4591001 1150 11501121/ Placebo	15/F/ WHITE	GENRL	Pyrexia/ Fever#	4	10JUN2021	1/2	1	Yes		NA	R (11JUN2021)	N/N
		MUSC	Myalgia/ Muscle Pain#	4	10JUN2021	1/2	1	Yes		NA	R (11JUN2021)	N/N
C4591001 1150 11501125/ Placebo	14/M/ BLACK OR AFRICAN AMERICAN	GENRL	Injection site pain/ Injection Site pain#	3	18MAY2021	1/2	1	Yes		NA	R (19MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	10JUN2021	1/2	1	Yes		NA	R (11JUN2021)	N/N
C4591001 1150 11501129/ Placebo	12/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	14MAY2021	2/3	2	Yes		NA	R (16MAY2021)	N/N
			Injection site pain/ Pain at injection site#	3	14MAY2021	2/3	2	Yes		NA	R (16MAY2021)	N/N

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Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1150 11501131/ Placebo	15/M/ WHITE	GENRL	Pain/ Body Aches#	3	14MAY2021	2/3	2	Yes		NA	R (16MAY2021)	N/N
			Pyrexia/ Fever#	3	14MAY2021	2/1	1	Yes		NA	R (14MAY2021)	N/N
			Fatigue/ Fatigue#	4	15MAR2021	1/2	2	Yes		NA	R (16MAR2021)	N/N
			Injection site pain/ Pain at injection site#	4	15MAR2021	1/2	2	Yes		NA	R (16MAR2021)	N/N
			Pain/ Generalized Body Aches#	4	15MAR2021	1/2	2	Yes		NA	R (16MAR2021)	N/N
			NERV Headache/ Headache#	4	15MAR2021	1/2	2	Yes		NA	R (16MAR2021)	N/N
			PSYCH Major depression/ Current severe episode of major depressive disorder without psychotic features without prior episode#	4	MAR2021	1/	3	No	O	NA/TC	R (10AUG2021)	Y/N
C4591001 1150 11501134/ Placebo	15/M/ WHITE	GENRL	Chills/ Chills#	3	18MAY2021	2/2	1	Yes		NA	R (19MAY2021)	N/N
C4591001 1150 11501166/ Placebo	14/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	21MAY2021	2/2	1	Yes		NA	R (22MAY2021)	N/N

**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1150 11501168/ BNT162b2 (30 µg)	13/M/ WHITE	MUSC	Myalgia/ Muscle Pain#	4	09JUN2021	2/2	2	Yes		NA	R (10JUN2021)	N/N
		PSYCH	Depression/ Depression	2	MAR2021	69/C	2	No	O	NA	RG	N/N
C4591001 1150 11501176/ Placebo	14/F/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	18MAY2021	1/3	2	Yes		NA	R (20MAY2021)	N/N
		GENRL	Chills/ Chills#	3	19MAY2021	2/1	1	Yes		NA	R (19MAY2021)	N/N
			Fatigue/ Fatigue#	3	19MAY2021	2/1	2	Yes		NA	R (19MAY2021)	N/N
		NERV	Syncope/ Fainting#	3	19MAY2021	2/1	2	Yes		NA	R (19MAY2021)	N/N
C4591001 1150 11501185/ Placebo	14/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	13MAY2021	1/2	1	Yes		NA	R (14MAY2021)	N/N
			Injection site bruising/ Bruise at injection site#	3	13MAY2021	1/5	1	Yes		NA	R (17MAY2021)	N/N
			Injection site pain/ Pain at injection site#	3	13MAY2021	1/2	1	Yes		NA	R (14MAY2021)	N/N
C4591001 1150	15/F/ WHITE	GASTR	Nausea/ Nausea#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Cause of Vax Rel <sup>c</sup> AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
11501189/ Placebo		GENRL	Fatigue/ Fatigue#	3	17MAY2021	1/2	1	Yes	NA	R (18MAY2021)	N/N
			Injection site pain/ Pain at injection site#	3	17MAY2021	1/2	2	Yes	NA	R (18MAY2021)	N/N
C4591001 1150 11501190/ Placebo	13/F/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	17MAY2021	1/2	1	Yes	NA	R (18MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	18MAY2021	2/1	1	Yes	NA	R (18MAY2021)	N/N
C4591001 1150 11501204/ Placebo	14/M/ WHITE	GENRL	Fatigue/ Fatigue#	3	17MAY2021	1/2	1	Yes	NA	R (18MAY2021)	N/N
C4591001 1150 11501207/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	18MAY2021	1/2	1	Yes	NA	R (19MAY2021)	N/N
C4591001 1150 11501210/ Placebo	12/F/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	24MAY2021	1/3	2	Yes	NA	R (26MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	14JUN2021	1/3	2	Yes	NA	R (16JUN2021)	N/N
			Injection site pain/ Pain at injection site#	4	14JUN2021	1/3	2	Yes	NA	R (16JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		MUSC	Arthralgia/ Generalized joint Pain##+	4	14JUN2021	1/3	1	Yes		NA	R (16JUN2021)	N/N
			Myalgia/ Muscle Pain#	4	14JUN2021	1/3	1	Yes		NA	R (16JUN2021)	N/N
		GENRL	Pyrexia/ Fever#	4	15JUN2021	2/1	1	Yes		NA	R (15JUN2021)	N/N
C4591001 1150 11501212/ Placebo	12/F/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	13MAY2021	1/2	1	Yes		NA	R (14MAY2021)	N/N
C4591001 1150 11501214/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ Injection Site pain#	3	19MAY2021	2/3	1	Yes		NA	R (21MAY2021)	N/N
		NERV	Headache/ Headache#	4	11JUN2021	2/2	1	Yes		NA	R (12JUN2021)	N/N
C4591001 1150 11501215/ Placebo	14/F/ WHITE	GENRL	Injection site pain/ Injection Site pain#	3	19MAY2021	2/2	1	Yes		NA	R (20MAY2021)	N/N
C4591001 1150 11501218/ Placebo	15/F/ WHITE	GENRL	Injection site pain/ Injection site pain#	3	18MAY2021	2/2	2	Yes		NA	RS (19MAY2021)	N/N
		NERV	Headache/ Headache#	4	09JUN2021	2/1	1	Yes		NA	R (09JUN2021)	N/N
C4591001 1150 11501222/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Pain at injection site#	4	01JUN2021	1/3	1	Yes		NA	R (03JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1150 11501224/ Placebo	12/M/ WHITE	GENRL	Fatigue/ Fatigue#	4	02JUN2021	2/2	1	Yes		NA	R (03JUN2021)	N/N
		NERV	Headache/ Headache#	4	02JUN2021	2/2	1	Yes		NA	R (03JUN2021)	N/N
		GENRL	Injection site pain/ Pain at injection site#	3	18MAY2021	1/3	1	Yes		NA	R (20MAY2021)	N/N
		GENRL	Chills/ Chills#	4	07JUN2021	1/2	1	Yes		NA	R (08JUN2021)	N/N
C4591001 1150 11501229/ Placebo	14/F/ WHITE		Fatigue/ Fatigue#	4	07JUN2021	1/2	1	Yes		NA	R (08JUN2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	14MAY2021	1/2	2	Yes		NA	R (15MAY2021)	N/N
			Injection site pain/ Pain at injection site#	3	14MAY2021	1/3	2	Yes		NA	R (16MAY2021)	N/N
			Pyrexia/ Fever#	3	14MAY2021	1/2	1	Yes		NA	R (15MAY2021)	N/N
		GENRL	Chills/ Chills#	4	02JUN2021	1/2	2	Yes		NA	R (03JUN2021)	N/N
			Fatigue/ Fatigue#	4	02JUN2021	1/3	2	Yes		NA	R (04JUN2021)	N/N
			Injection site erythema/ Redness at injection site#	4	02JUN2021	1/3	2	Yes		NA	R (04JUN2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
C4591001 1150 11501231/ Placebo	14/F/ ASIAN	NERV	Injection site pain/ Pain at injection site#	4	02JUN2021	1/3	2	Yes		NA	R (04JUN2021)	N/N	
			Pyrexia/ Fever#	4	02JUN2021	1/2	2	Yes		NA	R (03JUN2021)	N/N	
			Headache/ Headache#	4	02JUN2021	1/3	2	Yes		NA	R (04JUN2021)	N/N	
			Hand-foot-and- mouth disease/ Hand, foot and mouth disease#	4	10JUN2021	9/8	2	No	O	NA	R (17JUN2021)	N/N	
		GENRL	Fatigue/ Fatigue#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N	
			Injection site pain/ Pain at injection site#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N	
			Pain/ Body Aches#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N	
			Pyrexia/ Fever#	3	17MAY2021	1/1	1	Yes		NA	R (17MAY2021)	N/N	
			GENRL	Chills/ Chills#	3	19MAY2021	2/1	1	Yes		NA	R (19MAY2021)	N/N
				Pyrexia/ Fever (101.0)#	4	08JUN2021	2/1	1	Yes		NA	R (08JUN2021)	N/N
C4591001 1150	15/M/ WHITE	GENRL	Injection site pain/ Injection Site Pain#	4	08JUN2021	2/2	2	Yes		NA	R (09JUN2021)	N/N	

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
11501235/ Placebo C4591001 1150 11501242/ Placebo	15/M/ WHITE	GENRL	Fatigue/ Fatigue#	3	11MAR2021	2/2	1	Yes		NA	R (12MAR2021)	N/N
		GENRL	Fatigue/ Fatigue#	4	06APR2021	2/2	1	Yes		NA	R (07APR2021)	N/N
			Injection site pain/ Injection Site Pain#	4	06APR2021	2/2	1	Yes		NA	R (07APR2021)	N/N
		INJ&P	Traumatic renal injury/ Laceration of Left Kidney#	4	17JUL2021	104/C	2	No	O	NA	RG	Y/N
C4591001 1150 11501243/ Placebo	12/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	15MAY2021	2/2	1	Yes		NA	R (16MAY2021)	N/N
			Injection site pain/ Injection Site Pain#	3	15MAY2021	2/2	1	Yes		NA	R (16MAY2021)	N/N
		GENRL	Injection site pain/ Injection Site Pain#	4	04JUN2021	2/2	1	Yes		NA	R (05JUN2021)	N/N
C4591001 1150 11501248/ Placebo	13/M/ WHITE	INJ&P	Tibia fracture/ Broken Left Tibia	2	07APR2021	79/C	2	No	O	NA	RG	N/N
		GENRL	Injection site pain/ Pain at injection site#	3	19MAY2021	1/3	1	Yes		NA	R (21MAY2021)	N/N
		GENRL	Fatigue/ Fatigue#	3	20MAY2021	2/2	1	Yes		NA	R (21MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1150 11501249/ Placebo	15/M/ WHITE	GENRL	Injection site pain/ Injection Site Pain#	4	05JUN2021	2/2	2	Yes		NA	R (06JUN2021)	N/N
			Pyrexia/ Fever (100.7)#	4	05JUN2021	2/2	1	Yes		NA	R (06JUN2021)	N/N
C4591001 1150 11501250/ BNT162b2 (30 µg)	13/F/ NOT REPORTED	PSYCH	Suicidal ideation/ Suicidal Ideation	2	03MAR2021	44/5	2	No	O	NA/TC/TCN	R (07MAR2021)	Y/N
C4591001 1150 11501257/ Placebo	15/F/ WHITE	GENRL	Injection site pain/ Injection site pain#	3	15MAY2021	2/2	1	Yes		NA	R (16MAY2021)	N/N
C4591001 1150 11501261/ Placebo	13/M/ WHITE	GENRL	Fatigue/ Fatigue#	4	04JUN2021	2/1	2	Yes		NA	R (04JUN2021)	N/N
		NERV	Headache/ Headache#	4	04JUN2021	2/1	1	Yes		NA	R (04JUN2021)	N/N
C4591001 1150 11501263/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ Injection Site Pain#	3	20MAY2021	2/2	1	Yes		NA	R (21MAY2021)	N/N
		NERV	Headache/ Headache#	3	20MAY2021	2/2	1	Yes		NA	R (21MAY2021)	N/N
		GENRL	Injection site pain/ Injection Site Pain#	4	12JUN2021	2/2	2	Yes		NA	R (13JUN2021)	N/N
C4591001 1150	12/M/ WHITE	GENRL	Chills/ Chills#	3	15MAY2021	2/2	1	Yes		NA	R (16MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
11501271/ Placebo			Fatigue/ Fatigue#	3	15MAY2021	2/2	1	Yes		NA	R (16MAY2021)	N/N
		MUSC	Myalgia/ Muscle Pain#	4	03JUN2021	2/2	1	Yes		NA	R (04JUN2021)	N/N
C4591001 1150 11501272/ Placebo	14/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	15MAY2021	2/1	1	Yes		NA	R (15MAY2021)	N/N
C4591001 1150 11501280/ Placebo	14/F/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	19MAY2021	1/2	1	Yes		NA	R (20MAY2021)	N/N
		NERV	Headache/ Headache#	3	20MAY2021	2/1	2	Yes		NA	R (20MAY2021)	N/N
		MUSC	Myalgia/ Muscle Aches#	4	11JUN2021	2/1	1	Yes		NA	R (11JUN2021)	N/N
C4591001 1150 11501282/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ Pain at injection site#	3	17MAY2021	1/3	1	Yes		NA	R (19MAY2021)	N/N
		INFEC	Tinea infection/ Ringworm#	3	07JUN2021	22/C	1	No	O	NA	RG	N/N
C4591001 1150 11501284/ Placebo	14/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	17MAY2021	1/3	2	Yes		NA	R (19MAY2021)	N/N
			Injection site pain/ Pain at injection site#	3	17MAY2021	1/3	2	Yes		NA	R (19MAY2021)	N/N

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Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1150 11501291/ Placebo	15/M/ WHITE		Pain/ Body Aches#	3	17MAY2021	1/2	2	Yes		NA	R (18MAY2021)	N/N
			Pyrexia/ Fever#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
		NERV	Headache/ Headache#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
		GENRL	Pyrexia/ Fever (100.7)#	4	07JUN2021	1/4	1	Yes		NA	R (10JUN2021)	N/N
		MUSC	Myalgia/ Muscle Aches#	4	07JUN2021	1/4	2	Yes		NA	R (10JUN2021)	N/N
		GENRL	Injection site pain/ Pain at injection site#	3	19MAY2021	1/4	2	Yes		NA	R (22MAY2021)	N/Y
		GENRL	Fatigue/ Fatigue#	3	20MAY2021	2/3	2	Yes		NA	R (22MAY2021)	N/N
C4591001 1150 11501294/ Placebo	12/F/ BLACK OR AFRICAN AMERICAN	NERV	Headache/ Headache#	3	20MAY2021	2/2	2	Yes		NA	R (21MAY2021)	N/N
		EAR	Conductive deafness/ Left sided mild conductive hearing loss	1	14JAN2021	4/	2	Yes		NA	R	N/N
		GENRL	Injection site pain/ Pain at injection site#	3	27MAY2021	1/3	1	Yes		NA	R (29MAY2021)	N/N
			Injection site swelling/ Swollen at injection site#	3	27MAY2021	1/3	1	Yes		NA	R (29MAY2021)	N/N

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Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		GENRL	Injection site pain/ Pain at injection site#	4	16JUN2021	1/2	1	Yes		NA	R (17JUN2021)	N/N
C4591001 1150 11501298/ Placebo	13/M/ ASIAN	GENRL	Chills/ Chills#	3	14MAY2021	2/1	1	Yes		NA	R (14MAY2021)	N/N
			Pyrexia/ Fever#	3	14MAY2021	2/1	1	Yes		NA	R (14MAY2021)	N/N
		NERV	Headache/ Headache#	3	14MAY2021	2/1	1	Yes		NA	R (14MAY2021)	N/N
		GENRL	Chills/ Chills#	4	01JUN2021	1/1	1	Yes		NA	R (01JUN2021)	N/N
			Pyrexia/ Fever#	4	01JUN2021	1/1	1	Yes		NA	R (01JUN2021)	N/N
C4591001 1152 11521617/ BNT162b2 (30 µg)	13/M/ WHITE	INJ&P	Upper limb fracture/ Elbow Fracture#	2	01AUG2021	217/C	2	No	O	NA/TC/TCN	N	Y/N
C4591001 1152 11521664/ Placebo	13/F/ WHITE	INJ&P	Ankle fracture/ FRACTURED LEFT ANKLE	2	18JUN2021	171/C	2	No	O	NA/TC/TCN	N	N/N
			Fall/ FALL	2	18JUN2021	171/1	2	No	O	NA	R (18JUN2021)	N/N
C4591001 1152 11521669/ Placebo	15/F/ ASIAN	NERV	Headache/ headache	2	30MAR2021	91/1	1	No	O	NA	R (30MAR2021)	N/N

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Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1152 11521687/ Placebo	15/F/ WHITE	RESP	Nasal congestion/ Nasal Congestion	2	03MAY2021	118/C	2	No	O	NA/TC	N	N/N
C4591001 1152 11521688/ Placebo	12/F/ WHITE	RESP	Nasal congestion/ Nasal Congestion	2	01MAY2021	116/C	2	No	O	NA/TC	N	N/N
		GENRL	Chills/ Chills#	4	15JUN2021	2/2	2	Yes		NA/TC	R (16JUN2021)	N/N
			Fatigue/ fatigue#	4	15JUN2021	2/C	2	Yes		NA/TC	RG	N/N
		NERV	Headache/ headache#	4	15JUN2021	2/C	2	Yes		NA/TC	RG	N/N
C4591001 1152 11521690/ Placebo	14/F/ WHITE	INFEC	Ear infection/ Left ear infection#	3	11JUN2021	15/C	2	No	O	NA/TC/TCN	N	N/N
C4591001 1152 11521696/ Placebo	14/M/ WHITE	GENRL	Injection site pain/ site injection arm pain#	3	25MAY2021	2/2	2	Yes		NA/TC	R (26MAY2021)	N/N
		MUSC	Myalgia/ Myalgias#	3	25MAY2021	2/2	2	Yes		NA/TC	R (26MAY2021)	N/N
C4591001 1152 11521697/ BNT162b2 (30 µg)	12/F/ ASIAN	GENRL	Injection site pain/ Injection Site Pain	1	18DEC2020	1/4	2	Yes		NA/TC	R (21DEC2020)	N/N
		GENRL	Chills/ Chills	1	19DEC2020	2/1	2	Yes		NA	R (19DEC2020)	N/N

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			Fatigue/ Fatigue	1	19DEC2020	2/1	2	Yes		NA	R (19DEC2020)	N/N
			Injection site swelling/ Injection Site Swelling	1	19DEC2020	2/2	2	Yes		NA	R (20DEC2020)	N/N
			Pyrexia/ Fever	1	19DEC2020	2/1	1	Yes		NA/TC	R (19DEC2020)	N/N
C4591001 1152 11521739/ Placebo	12/M/ WHITE	MUSC	Musculoskeletal stiffness/ Left arm stiffness#	3	22MAY2021	2/7	1	Yes		NA	R (28MAY2021)	N/N
C4591001 1152 11521740/ Placebo	15/F/ WHITE	GENRL	Fatigue/ fatigue#	3	25MAY2021	2/2	2	Yes		NA/TC	R (26MAY2021)	N/N
			Injection site pain/ site injection arm pain#	3	25MAY2021	2/C	2	Yes		NA/TC	RG	N/N
C4591001 1152 11521752/ Placebo	15/M/ ASIAN	INJ&P	Joint injury/ left wrist joint injured#	3	26MAY2021	2/C	1	No	O	NA/TCN	RG	N/N
C4591001 1156 11561357/ Placebo	12/F/ WHITE	INFEC	Appendicitis/ APPENDICITIS#	4	10JUN2021	4/1	2	Yes		NA/TC	R (10JUN2021)	Y/N
C4591001 1223 12231269/ Placebo	15/F/ WHITE	GENRL	Fatigue/ fatigue#	3	21MAY2021	2/2	1	Yes		NA/TCN	R (22MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1223 12231273/ Placebo	15/M/ WHITE	CARD	Myocarditis/ Myopericarditis#	4	12JUN2021	3/2	3	No	O	NA/TC	R (13JUN2021)	Y/N
C4591001 1223 12231277/ Placebo	12/M/ WHITE	GENRL	Injection site pain/ injection site pain#	3	26MAY2021	2/2	1	Yes		NA	R (27MAY2021)	N/N
		GENRL	Pyrexia/ fever#	4	14JUN2021	1/3	1	Yes		NA/TC	R (16JUN2021)	N/N
		NERV	Headache/ headache#	4	14JUN2021	1/3	1	Yes		NA	R (16JUN2021)	N/N
C4591001 1223 12231279/ Placebo	13/F/ WHITE	GENRL	Fatigue/ fatigue#	4	11JUN2021	1/3	1	Yes		NA	R (13JUN2021)	N/N
		MUSC	Pain in extremity/ sore arm#	4	11JUN2021	1/3	1	Yes		NA/TC	R (13JUN2021)	N/N
C4591001 1223 12231283/ Placebo	14/M/ WHITE	GENRL	Fatigue/ fatigue#	3	20MAY2021	1/2	1	Yes		NA	R (21MAY2021)	N/N
			Injection site pain/ injection site pain#	3	20MAY2021	1/3	1	Yes		NA	R (22MAY2021)	N/N
C4591001 1223 12231286/ Placebo	15/F/ WHITE	GENRL	Fatigue/ fatigue#	3	21MAY2021	1/3	1	Yes		NA	R (23MAY2021)	N/N
			Pyrexia/ fever#	3	21MAY2021	1/2	1	Yes		NA/TC	R (22MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1235 12351235/ Placebo	13/M/ WHITE	GENRL	Fatigue/ fatigue#	4	11JUN2021	1/2	1	Yes		NA	R (12JUN2021)	N/N
			Injection site pain/ injection site pain#	4	11JUN2021	1/2	1	Yes		NA	R (12JUN2021)	N/N
		INFEC	Paronychia/ ingrown toenail infection#	3	24MAY2021	7/15	2	No	O	NA/TC/TCN	R (07JUN2021)	N/N
			Skin candida/ cutaneous candidiasis#	3	24MAY2021	7/15	2	No	O	NA/TC	R (07JUN2021)	N/N
		GENRL	Adverse drug reaction/ antibiotic side effect#	3	02JUN2021	16/4	2	No	O	NA	R (05JUN2021)	N/N
C4591001 1235 12351252/ Placebo	13/M/ WHITE	SKIN	Urticaria/ allergic urticaria#	4	27JUN2021	20/3	2	No	O	NA/TC	R (29JUN2021)	N/N
C4591001 1270 12701173/ Placebo	15/F/ WHITE	GENRL	Fatigue/ Fatigue#	3	13MAY2021	1/3	1	Yes		NA	R (15MAY2021)	N/N
			Injection site pain/ Injection Site Pain#	3	13MAY2021	1/2	1	Yes		NA	R (14MAY2021)	N/N
			Pain/ Generalized Body Aches#	3	13MAY2021	1/3	1	Yes		NA	R (15MAY2021)	N/N
C4591001 1270	15/F/ WHITE	MUSC	Back pain/ Low Back Pain	2	22FEB2021	63/36	1	No	O	NA	R (29MAR2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
12701181/ Placebo C4591001 1270	13/M/ ASIAN	GENRL	Fatigue/ Fatigue#	3	18MAY2021	1/2	1	Yes		NA	R (19MAY2021)	N/N
12701188/ Placebo		NERV	Headache/ Headache#	3	18MAY2021	1/2	1	Yes		NA	R (19MAY2021)	N/N
C4591001 1270 12701200/ BNT162b2 (30 µg)	13/M/ WHITE	INFEC	Anal abscess/ PERIANAL ABSCESS	2	16MAR2021	78/C	3	No	O	NA/TC/TCN	RG	Y/N
C4591001 1270 12701202/ BNT162b2 (30 µg)	15/M/ WHITE	INFEC	Paronychia/ Left finger paronychia	2	17MAR2021	77/9	1	No	O	NA/TC	R (25MAR2021)	N/N
C4591001 1270 12701204/ Placebo	12/M/ NOT REPORTED	GENRL	Chills/ Chills#	3	18MAY2021	2/1	1	Yes		NA/TC	R (18MAY2021)	N/N
			Injection site pain/ Injection site pain#	3	18MAY2021	2/1	1	Yes		NA/TC	R (18MAY2021)	N/N
			Pyrexia/ Fever#	3	18MAY2021	2/1	2	Yes		NA/TC	R (18MAY2021)	N/N
C4591001 1270 12701205/ Placebo	13/F/ MULTIPLE	GENRL	Injection site pain/ Injection site pain#	3	17MAY2021	1/4	1	Yes		NA/TC	R (20MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1270 12701206/ Placebo	15/F/ WHITE	SKIN	Ingrowing nail/ Right Ingrown Toenail#	3	09JUN2021	24/22	1	No	O	NA/TC	R (30JUN2021)	N/N
		GENRL	Fatigue/ FATIGUE#	3	27MAY2021	2/1	2	Yes		NA	R (27MAY2021)	N/N
			Injection site pain/ Injection site pain#	3	27MAY2021	2/1	1	Yes		NA	R (27MAY2021)	N/N
C4591001 1270 12701208/ Placebo	14/F/ WHITE	INJ&P	Ligament sprain/ RIHT WRIST SPRAIN#	4	14JUL2021	29/C	1	No	O	NA/TC/TCN	RG	N/N
		INJ&P	Concussion/ Concussion without loss of conciousness	2	11MAR2021	65/	2	No	O	NA/TCN	R	N/N
			Hand fracture/ Left Middle Finger Middle Phalanx Fracture	2	11MAR2021	65/70	2	No	O	NA/TCN	R (19MAY2021)	N/N
C4591001 1270 12701213/ Placebo	12/F/ WHITE	GASTR	Abdominal pain/ Chronic Abdominal Pain	2	JAN2021	1/C	1	No	O	NA/TC	N	N/N
		MUSC	Tendonitis/ tendinitis of Left Ankle	2	JAN2021	1/C	1	No	O	NA/TC/TCN	RG	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1270 12701216/ Placebo	12/F/ MULTIPLE	GENRL	Fatigue/ Fatigue#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
			Injection site pain/ Injection site pain#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
		NERV	Headache/ Headache#	3	17MAY2021	1/2	1	Yes		NA	R (18MAY2021)	N/N
		NERV	Syncope/ Syncope#	2	17MAY2021	132/1	2	No	O	NA/TCN	R (17MAY2021)	N/N
C4591001 1270 12701217/ Placebo	12/F/ WHITE	NEOPL	Melanocytic naevus/ Melanocytic Nevus	2	10FEB2021	34/C	1	No	O	NA	N	N/N
		SKIN	Acne/ Acne Vulgaris	2	10FEB2021	34/C	1	No	O	NA/TC	RG	N/N
			Seborrheic dermatitis/ Seborrheic Dermatitis to scalp	2	10FEB2021	34/C	1	No	O	NA/TC	RG	N/N
C4591001 1270 12701221/ Placebo	12/F/ WHITE	GENRL	Injection site pain/ Injection site pain#	3	17MAY2021	1/3	1	Yes		NA	R (19MAY2021)	N/N
		GENRL	Chills/ Chills#	3	26MAY2021	1/2	1	Yes		NA	R (27MAY2021)	N/N
C4591001 1270	13/M/ WHITE	EAR	Ear pain/ Right otalgia#	4	02JUL2021	19/7	1	No	O	NA/TC	R (08JUL2021)	N/N
		GENRL	Pain/ Body Aches#	3	21MAY2021	2/2	1	Yes		NA	R (22MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
12701223/ Placebo			Pyrexia/ Fever#	3	21MAY2021	2/2	1	Yes		NA	R (22MAY2021)	N/N
C4591001 1270 12701227/ Placebo	13/M/ ASIAN	MUSC	Myalgia/ Generalized Myalgia#	3	19MAY2021	2/1	1	Yes		NA/TC	R (19MAY2021)	N/N
		NERV	Headache/ Headache#	3	19MAY2021	2/1	1	Yes		NA/TC	R (19MAY2021)	N/N
C4591001 1270 12701228/ Placebo	12/F/ WHITE	RENAL	Dysuria/ Dysuria#	4	09JUN2021	7/3	1	No	O	NA	R (11JUN2021)	N/N
C4591001 1270 12701237/ Placebo	13/F/ AMERICAN INDIAN OR ALASKA NATIVE	SKIN	Rash/ Rash on Right Foot	1	05APR2021	89/4	1	No	O	NA/TC	R (08APR2021)	N/N
		GASTR	Nausea/ INTERMITTENT NAUSEA#	3	19MAY2021	1/56	2	Yes		NA	R (13JUL2021)	N/N
		GENRL	Chills/ CHILLS#	3	19MAY2021	1/3	1	Yes		NA/TC	R (21MAY2021)	N/N
			Non-cardiac chest pain/ INTERMITTENT NON-CARDIAC CHEST DISCOMFORT#	3	19MAY2021	1/56	2	Yes		NA/TC	R (13JUL2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1270 12701241/ Placebo	13/M/ WHITE	NERV	Headache/ INTERMITTENT HEADACHES#	3	19MAY2021	1/56	2	Yes		NA/TC	R (13JUL2021)	N/N
		GENRL	Pyrexia/ Fever#	3	20MAY2021	2/2	1	Yes		NA/TC	R (21MAY2021)	N/N
		GASTR	Abdominal pain upper/ INTERMITTENT STOMACH PAIN#	3	25MAY2021	7/50	2	Yes		NA	R (13JUL2021)	N/N
		GENRL	Fatigue/ FATIGUE#	3	25MAY2021	7/50	3	Yes		NA	R (13JUL2021)	N/N
			Thirst/ INCREASED THIRST#	3	25MAY2021	7/19	1	Yes		NA	R (12JUN2021)	N/N
		METAB	Decreased appetite/ LOSS OF APPETITE#	3	25MAY2021	7/50	2	Yes		NA	R (13JUL2021)	N/N
		INFEC	Otitis media/ LEFT OTITIS MEDIA#	3	29JUN2021	42/8	1	No	O	NA/TC	R (06JUL2021)	N/N
		GENRL	Chills/ Chills#	3	19MAY2021	1/2	1	Yes		NA	R (20MAY2021)	N/N
			Pyrexia/ Fever#	3	19MAY2021	1/2	1	Yes		NA/TC	R (20MAY2021)	N/N
C4591001 1270	14/F/ WHITE	NERV	Headache/ Headache#	3	19MAY2021	1/2	1	Yes		NA/TC	R (20MAY2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	3	18MAY2021	1/2	1	Yes		NA/TC	R (19MAY2021)	N/N

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**16.2.7.2.3 Listing of New Adverse Events After the EUA Snapshot – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade Rel <sup>c</sup>	Cause of Investigational Vaccine Dose/ Subject	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
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12701244/  
Placebo

Abbreviations: C = continuing; Dur = duration; Imm = immediate; EUA = emergency use authorization. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v24.0) coding dictionary applied.

Note: \* = prevaccination AE, # = AE occurring on or after subject unblinding, + = new arthralgia after the EUA snapshot.

Note: For original placebo group subjects, Dose 3 = first dose of BNT162b2 (30 µg), Dose 4 = second dose of BNT162b2 (30 µg).

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

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (17:29) Source Data: adae Table Generation: 08NOV2021 (19:56)

(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2\_unblinded/C4591001\_S\_Peds/adae\_1002\_1\_n\_ped6

## 16.2.7.4 Listing of Serious Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1005 10051449/ BNT162b2 (30 µg)	14/M/ WHITE	INFEC	Appendicitis/ Appendicitis#	2	28JUN2021	148/2	2	No	O	NA/TCN	R (29JUN2021)	Y/N
C4591001 1006 10061272/ BNT162b2 (30 µg)	13/F/ BLACK OR AFRICAN AMERICAN	PSYCH	Anxiety/ Worsening of anxiety	1	23DEC2020	8/27	3	No	O	NA/TC/TCN	R (18JAN2021)	Y/N
			Depression/ Worsening of Depression	1	23DEC2020	8/27	3	No	O	NA/TC/TCN	R (18JAN2021)	Y/N
C4591001 1007 10071505/ Placebo	12/F/ WHITE	NERV	Somnolence/ Excessive Sleepiness#	4	08JUL2021	16/15	3	No	O	NA	R (22JUL2021)	Y/N
C4591001 1007 10071581/ Placebo	15/M/ WHITE	INFEC	Appendicitis/ Appendicitis	2	10MAR2021	63/20	3	No	O	NA/TC	R (29MAR2021)	Y/N
C4591001 1007 10071600/ Placebo	12/F/ WHITE	PSYCH	Depression/ depression#	2	17MAY2021	119/C	2	No	O	NA/TC	RG	Y/N
			Suicidal ideation/ Suicidal Ideation#	2	17MAY2021	119/5	3	No	O	NA/TC/TCN	R (21MAY2021)	Y/N
C4591001 1007 10071620/ BNT162b2 (30 µg)	12/F/ WHITE	PSYCH	Conversion disorder/ generalized Functional neurologic disorder	2	21JAN2021	2/C	2	No	O	NA/TC	N	Y/N
C4591001 1007 10071620/ BNT162b2 (30 µg)	12/F/ WHITE	GASTR	Abdominal pain/ Functional Abdominal Pain	2	28FEB2021	40/C	3	No	O	NA/TC	N	Y/N

## 16.2.7.4 Listing of Serious Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Constipation/ Constipation	2	28FEB2021	40/14	3	No	O	NA/TC	R (13MAR2021)	Y/N
C4591001 1009 10091413/ BNT162b2 (30 µg)	13/F/ WHITE	INJ&P	Femur fracture/ Right Intertrochanteric Femur Fracture	2	13MAR2021	39/4	3	No	O	NA/TC/TCN	R (16MAR2021)	Y/N
C4591001 1016 10161327/ Placebo	12/M/ WHITE	NERV	Epilepsy/ epilepsy#	4	29JUN2021	8/C	2	No	O	NA	N	Y/N
C4591001 1039 10391326/ BNT162b2 (30 µg)	15/M/ ASIAN	PSYCH	Depression/ Depression Exacerbation	1	26JAN2021	16/5	3	No	O	NA/TC/TCN	R (30JAN2021)	Y/N
C4591001 1039 10391326/ BNT162b2 (30 µg)	15/M/ ASIAN	PSYCH	Depression/ Depression Exacerbation	2	29MAR2021	57/5	3	No	O	NA/TC/TCN	R (02APR2021)	Y/N
C4591001 1039 10391332/ BNT162b2 (30 µg)	13/F/ WHITE	PSYCH	Suicidal ideation/ Active Suicidal Ideation	2	12APR2021	70/10	4	No	O	NA/TC/TCN	R (21APR2021)	Y/N
C4591001 1091 10911447/ BNT162b2 (30 µg)	15/M/ WHITE	INFEC	Appendicitis/ Appendicitis#	2	09JUL2021	177/2	2	No	O	NA/TCN	R (10JUL2021)	Y/N
C4591001 1123 11231507/ BNT162b2 (30 µg)	14/F/ WHITE	PSYCH	Depression/ Worsening of Depression	2	19JAN2021	2/5	2	No	O	NA/TC	R (23JAN2021)	Y/N

## 16.2.7.4 Listing of Serious Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1140 11401354/ BNT162b2 (30 µg)	15/F/ WHITE	CONG	Syringomyelia/ Thoracic spinal syrinx#	2	JUN2021	140/C	3	No	O	NA/TC/TCN	N	Y/N
C4591001 1140 11401365/ BNT162b2 (30 µg)	15/M/ WHITE	PSYCH	Suicidal ideation/ Suicidal Ideation	2	04APR2021	76/2	3	No	O	NA/TC/TCN	R (05APR2021)	Y/N
C4591001 1147 11471281/ Placebo	13/M/ WHITE	INFEC	Appendicitis/ Acute appendicitis	2	22JAN2021	19/2	4	No	O	NA/TC/TCN	R (23JAN2021)	Y/N
			Focal peritonitis/ localized peritonitis, without perforation or gangrene	2	22JAN2021	19/2	4	No	O	NA/TC/TCN	R (23JAN2021)	Y/N
C4591001 1150 11501131/ Placebo	15/M/ WHITE	PSYCH	Major depression/ Current severe episode of major depressive disorder without psychotic features without prior episode#	4	MAR2021	1/	3	No	O	NA/TC	R (10AUG2021)	Y/N
C4591001 1150 11501242/ Placebo	15/M/ WHITE	INJ&P	Traumatic renal injury/ Laceration of Left Kidney#	4	17JUL2021	104/C	2	No	O	NA	RG	Y/N
C4591001 1150 11501250/ BNT162b2 (30 µg)	13/F/ NOT REPORTED	PSYCH	Suicidal ideation/ Suicidal Ideation	2	03MAR2021	44/5	2	No	O	NA/TC/TCN	R (07MAR2021)	Y/N
C4591001 1152 11521617/	13/M/ WHITE	INJ&P	Upper limb fracture/ Elbow Fracture#	2	01AUG2021	217/C	2	No	O	NA/TC/TCN	N	Y/N

## 16.2.7.4 Listing of Serious Adverse Events – All Subjects 12 Through 15 Years of Age

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
BNT162b2 (30 µg)												
C4591001 1156 11561357/ Placebo	12/F/ WHITE	INFEC	Appendicitis/ APPENDICITIS#	4	10JUN2021	4/1	2	Yes		NA/TC	R (10JUN2021)	Y/N
C4591001 1223 12231273/ Placebo	15/M/ WHITE	CARD	Myocarditis/ Myopericarditis#	4	12JUN2021	3/2	3	No	O	NA/TC	R (13JUN2021)	Y/N
C4591001 1270 12701200/ BNT162b2 (30 µg)	13/M/ WHITE	INFEC	Anal abscess/ PERIANAL ABSCESS	2	16MAR2021	78/C	3	No	O	NA/TC/TCN	RG	Y/N
C4591001 1270 12701222/ BNT162b2 (30 µg)	14/F/ WHITE	PSYCH	Suicidal ideation/ SUICIDAL IDEATION	2	16FEB2021	40/28	3	No	O	NA/TC/TCN	R (15MAR2021)	Y/N

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v24.0) coding dictionary applied.

Note: # = AE occurring on or after subject unblinding date.

Note: For original placebo group subjects, Dose 3 = first dose of BNT162b2 (30 µg), Dose 4 = second dose of BNT162b2 (30 µg).

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

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (17:29) Source Data: adae Table Generation: 08NOV2021 (19:56)

(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2\_unblinded/C4591001\_S\_Peds/adae\_1002\_sae1\_ped6

**16.2.7.5 Listing of Adverse Events Leading to Discontinuation – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action:	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Investigator Text							Investigational Vaccine Dose/ Subject		
C4591001 1147 11471327/ BNT162b2 (30 µg)	14/M/ WHITE	GENRL	Pyrexia/ Fever (104.7)	1	06JAN2021	2/3	4	Yes		P/TC	R (08JAN2021)	N/N

Abbreviations: Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v24.0) coding dictionary applied.

- a. Relative day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.
- b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.
- c. Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (17:29) Source Data: adae Table Generation: 08NOV2021 (19:56)

(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2\_unblinded/C4591001\_S\_Peds/adae\_1002\_disc1\_ped6

### 16.2.7.6 Listing of Deaths – All Subjects 12 Through 15 Years of Age

<b>Subject/ Vaccine Group (as Administered)</b>	<b>Dose No.</b>	<b>Rel Day<sup>a</sup></b>	<b>Sex/Race</b>	<b>Date of Death</b>	<b>Age at Death (Years)</b>	<b>Primary Cause of Death</b>	<b>Secondary Cause(s) of Death</b>
No subject meets the reporting criteria.							

Note: MedDRA (v24.0) coding dictionary applied.

a. Relative day (Rel Day) = date of death - date of last vaccination + 1.

PFIZER CONFIDENTIAL SDTM Creation: 30SEP2021 (10:35) Source Data: adsl Table Generation: 08NOV2021 (22:21)

(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2\_unblinded/C4591001\_S\_Peds/cdl\_dth1\_ped6

**16.2.7.7 Listing of Subjects Reporting Pregnancy After Dose 1 – All Subjects 12 Through 15 Years of Age**

<b>Subject</b>	<b>Race</b>	<b>Dose No.</b>	<b>Rel Day<sup>a</sup></b>	<b>Date of Pregnancy</b>	<b>Age at Pregnancy (Years)</b>
No subject meets the reporting criteria.					

Note: MedDRA (v24.0) coding dictionary applied.

a. Relative day (Rel Day) = date of pregnancy - date of last vaccination before pregnancy + 1.

PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (18:29) Source Data: adae Table Generation: 03NOV2021 (14:34)

(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2\_unblinded/C4591001\_S\_Peds/adae\_l002\_prg1\_ped6

**16.2.7.8 Listing of Subjects Reporting Lymphadenopathy After Dose 1 – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1007 10071497/ BNT162b2 (30 µg)	12/M/ ASIAN	BLOOD	Lymphadenopathy/ swollen lymph node left axilla	2	25DEC2020	4/27	1	Yes		NA	R (20JAN2021)	N/N
C4591001 1007 10071615/ BNT162b2 (30 µg)	12/M/ WHITE	BLOOD	Lymphadenopathy/ left axillary lymph node swelling	2	20JAN2021	2/4	1	Yes		NA	R (23JAN2021)	N/N
C4591001 1007 10071651/ BNT162b2 (30 µg)	12/M/ WHITE	BLOOD	Lymphadenopathy/ Left deep cervical chain lymph node swelling	1	12JAN2021	8/29	1	Yes		NA	R (09FEB2021)	N/N
C4591001 1007 10071651/ BNT162b2 (30 µg)	12/M/ WHITE	BLOOD	Lymphadenopathy/ left Cervical lymphadenopathy	2	23FEB2021	29/15	1	No	O	NA	R (09MAR2021)	N/N
C4591001 1009 10091231/ BNT162b2 (30 µg)	15/M/ ASIAN	BLOOD	Lymphadenopathy/ left swollen axillary lymph node	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
C4591001 1009 10091342/ BNT162b2 (30 µg)	15/M/ WHITE	BLOOD	Lymphadenopathy/ swollen cervical lymph nodes bilateral	2	31JAN2021	28/3	1	No	O	NA	R (02FEB2021)	N/N

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**16.2.7.8 Listing of Subjects Reporting Lymphadenopathy After Dose 1 – All Subjects 12 Through 15 Years of Age**

Subject/ Vaccine Group (as Administered)	Age(Years)/ Sex/ Race	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
C4591001 1009 10091405/ Placebo	15/F/ WHITE	BLOOD	Lymphadenopathy/ left axillary adenopathy#	4	20AUG2021	2/C	1	Yes		NA	N	N/N
C4591001 1016 10161344/ Placebo	15/F/ WHITE	BLOOD	Lymphadenopathy/ enlarged lymph nodes, right anterior cervical nodes	2	25NOV2020	15/43	1	No	O	NA	R (06JAN2021)	N/N
C4591001 1126 11261263/ BNT162b2 (30 µg)	15/M/ WHITE	BLOOD	Lymphadenopathy/ LEFT AXILLA LYMPH NODE SWELLING	1	10DEC2020	7/4	1	Yes		NA	R (13DEC2020)	N/N
C4591001 1131 11311287/ Placebo	12/F/ BLACK OR AFRICAN AMERICAN	BLOOD	Lymphadenopathy/ enlarge lymph nods- neck(bilateral)	2	27JAN2021	10/8	1	Yes		NA	R (03FEB2021)	N/N
C4591001 1142 11421385/ BNT162b2 (30 µg)	15/M/ NOT REPORTED	BLOOD	Lymphadenopathy/ left supraclavicular lymph node swelling	1	07JAN2021	8/8	1	Yes		NA	R (14JAN2021)	N/N
C4591001 1152 11521683/ BNT162b2 (30 µg)	14/F/ WHITE	BLOOD	Lymphadenopathy/ Swollen Lymph Node (Left Clavicle)	1	26DEC2020	12/C	1	No	O	NA	N	N/N
C4591001 1152 11521704/	14/M/ WHITE	BLOOD	Lymphadenopathy/ swollen lymph node left axilla	1	26DEC2020	6/10	2	Yes		NA	R (04JAN2021)	N/N

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**16.2.7.8 Listing of Subjects Reporting Lymphadenopathy After Dose 1 – All Subjects 12 Through 15 Years of Age**

<b>Subject/ Vaccine Group (as Administered)</b>	<b>Age(Years)/ Sex/ Race</b>	<b>System Organ Class</b>	<b>Preferred Term/ AE Investigator Text</b>	<b>Dose No.</b>	<b>Onset Date</b>	<b>Rel Day<sup>a</sup>/ Dur (Days)<sup>b</sup></b>	<b>Toxicity Vax Grade Rel<sup>c</sup></b>	<b>AE</b>	<b>Action: Investigational Cause of Vaccine Dose/ Subject</b>	<b>Outcome (End Date)</b>	<b>SAE/Imm AE (Yes/No)</b>
BNT162b2 (30 µg)											
Abbreviations: Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.											
Note: MedDRA (v24.0) coding dictionary applied.											
Note: For original placebo group subjects, Dose 3 = first dose of BNT162b2 (30 µg), Dose 4 = second dose of BNT162b2 (30 µg).											
a. Relative day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.											
b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.											
c. Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.											
PFIZER CONFIDENTIAL SDTM Creation: 05OCT2021 (17:29) Source Data: adae Table Generation: 08NOV2021 (22:28)											
(Data Cutoff Date: 02SEP2021, Database Snapshot Date: 27SEP2021) Output File: ./nda2_unblinded/C4591001_S_Peds/adae_1002_lym1_ped6											