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16.1.7.2.1 Listing of Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – 12 Through 15 Years of Age – Safety Population

Subject	Date	Vaccine Received		Date	Dose 3	Date	Dose 4
		Dose 1	Dose 2	Date of Unblinding			
C4591001 1005 10051419	16DEC2020	Placebo	04JAN2021	Placebo	15FEB2021	24FEB2021	BNT162b2 (30 µg)
C4591001 1006 10061229	08DEC2020	Placebo	29DEC2020	Placebo	15FEB2021	18FEB2021	BNT162b2 11MAR2021 BNT162b2 (30 µg) (30 µg)
C4591001 1006 10061257	11DEC2020	Placebo	30DEC2020	Placebo	15FEB2021	19FEB2021	BNT162b2 12MAR2021 BNT162b2 (30 µg) (30 µg)
C4591001 1006 10061266	15DEC2020	Placebo	06JAN2021	Placebo	23FEB2021	24FEB2021	BNT162b2 (30 µg)
C4591001 1006 10061270	16DEC2020	Placebo	06JAN2021	Placebo	15FEB2021	18FEB2021	BNT162b2 11MAR2021 BNT162b2 (30 µg) (30 µg)
C4591001 1007 10071524	08DEC2020	Placebo	29DEC2020	Placebo	10FEB2021	25FEB2021	BNT162b2 (30 µg)
C4591001 1007 10071541	09DEC2020	Placebo	30DEC2020	Placebo	08FEB2021	09FEB2021	BNT162b2 02MAR2021 BNT162b2 (30 µg) (30 µg)
C4591001 1008 10081858	28DEC2020	Placebo	19JAN2021	Placebo	16FEB2021	17FEB2021	BNT162b2 08MAR2021 BNT162b2 (30 µg) (30 µg)
C4591001 1008 10081901	05JAN2021	Placebo	26JAN2021	Placebo	12FEB2021	15FEB2021	BNT162b2 08MAR2021 BNT162b2 (30 µg) (30 µg)
C4591001 1009 10091208	15OCT2020	Placebo	06NOV2020	Placebo	22FEB2021	05MAR2021	BNT162b2 (30 µg)
C4591001 1009 10091213	16OCT2020	Placebo	04NOV2020	Placebo	16FEB2021	22FEB2021	BNT162b2 (30 µg)
C4591001 1009 10091266	01DEC2020	Placebo	21DEC2020	Placebo	22FEB2021	04MAR2021	BNT162b2 (30 µg)
C4591001 1009 10091344	15DEC2020	Placebo	04JAN2021	Placebo	24FEB2021	01MAR2021	BNT162b2 (30 µg)

16.1.7.2.1 Listing of Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – 12 Through 15 Years of Age – Safety Population

Subject	Date	Vaccine Received							
		Dose 1	Date	Dose 2	Date of Unblinding	Date	Dose 3	Date	Dose 4
C4591001 1009 10091384	05JAN2021	Placebo	25JAN2021	Placebo	19FEB2021	23FEB2021	BNT162b2 (30 µg)		
C4591001 1009 10091403	08JAN2021	Placebo	27JAN2021	Placebo	22FEB2021	24FEB2021	BNT162b2 (30 µg)		
C4591001 1016 10161316	16OCT2020	Placebo			23FEB2021	25FEB2021	BNT162b2 (30 µg)		
C4591001 1039 10391246	01DEC2020	Placebo	21DEC2020	Placebo	23FEB2021	26FEB2021	BNT162b2 (30 µg)		
C4591001 1039 10391251	07DEC2020	Placebo	04JAN2021	Placebo	02FEB2021	02FEB2021	BNT162b2 (30 µg)	25FEB2021	BNT162b2 (30 µg)
C4591001 1044 10441274	08DEC2020	Placebo	28DEC2020	Placebo	09FEB2021	17FEB2021	BNT162b2 (30 µg)	12MAR2021	BNT162b2 (30 µg)
C4591001 1044 10441280	09DEC2020	Placebo	29DEC2020	Placebo	26JAN2021	28JAN2021	BNT162b2 (30 µg)	17FEB2021	BNT162b2 (30 µg)
C4591001 1044 10441282	09DEC2020	Placebo	30DEC2020	Placebo	22FEB2021	03MAR2021	BNT162b2 (30 µg)		
C4591001 1044 10441292	17DEC2020	Placebo	05JAN2021	Placebo	08MAR2021	10MAR2021	BNT162b2 (30 µg)		
C4591001 1044 10441344	09JAN2021	Placebo	29JAN2021	Placebo	10FEB2021	19FEB2021	BNT162b2 (30 µg)		
C4591001 1044 10441368	11JAN2021	Placebo	03FEB2021	Placebo	08MAR2021	09MAR2021	BNT162b2 (30 µg)		
C4591001 1057 10571391	09DEC2020	Placebo	28DEC2020	Placebo	19FEB2021	24FEB2021	BNT162b2 (30 µg)		
C4591001 1057 10571402	14DEC2020	Placebo	06JAN2021	Placebo	15FEB2021	03MAR2021	BNT162b2 (30 µg)		

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16.1.7.2.1 Listing of Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – 12 Through 15 Years of Age – Safety Population

Subject	Date	Vaccine Received							
		Dose 1	Date	Dose 2	Date of Unblinding	Date	Dose 3	Date	Dose 4
C4591001 1057 10571407	17DEC2020	Placebo	05JAN2021	Placebo	12FEB2021	12MAR2021	BNT162b2 (30 µg)		
C4591001 1077 10771295	28DEC2020	Placebo	20JAN2021	Placebo	22FEB2021	25FEB2021	BNT162b2 (30 µg)		
C4591001 1123 11231454	15DEC2020	Placebo	07JAN2021	Placebo	15FEB2021	20FEB2021	BNT162b2 (30 µg)		
C4591001 1123 11231460	17DEC2020	Placebo	08JAN2021	Placebo	15FEB2021	17FEB2021	BNT162b2 (30 µg)	10MAR2021	BNT162b2 (30 µg)
C4591001 1124 11241270	05JAN2021	Placebo	26JAN2021	Placebo	23FEB2021	23FEB2021	BNT162b2 (30 µg)		
C4591001 1126 11261262	04DEC2020	Placebo	23DEC2020	Placebo	09FEB2021	10FEB2021	BNT162b2 (30 µg)	03MAR2021	BNT162b2 (30 µg)
C4591001 1126 11261275	15DEC2020	Placebo	06JAN2021	Placebo	04FEB2021	08FEB2021	BNT162b2 (30 µg)	03MAR2021	BNT162b2 (30 µg)
C4591001 1126 11261276	15DEC2020	Placebo	06JAN2021	Placebo	04FEB2021	08FEB2021	BNT162b2 (30 µg)	03MAR2021	BNT162b2 (30 µg)
C4591001 1126 11261305	30DEC2020	Placebo	21JAN2021	Placebo	22FEB2021	24FEB2021	BNT162b2 (30 µg)		
C4591001 1139 11391166	11DEC2020	Placebo	30DEC2020	Placebo	08FEB2021	16FEB2021	BNT162b2 (30 µg)	11MAR2021	BNT162b2 (30 µg)
C4591001 1139 11391181	18DEC2020	Placebo	07JAN2021	Placebo	09FEB2021	15FEB2021	BNT162b2 (30 µg)	08MAR2021	BNT162b2 (30 µg)
C4591001 1139 11391212	28DEC2020	Placebo	19JAN2021	Placebo	12FEB2021	19FEB2021	BNT162b2 (30 µg)		
C4591001 1139 11391235	05JAN2021	Placebo	28JAN2021	Placebo	08FEB2021	15FEB2021	BNT162b2 (30 µg)	08MAR2021	BNT162b2 (30 µg)

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Subject	Date	Vaccine Received							
		Dose 1	Date	Dose 2	Date of Unblinding	Date	Dose 3	Date	Dose 4
C4591001 1139 11391263	12JAN2021	Placebo	01FEB2021	Placebo	09FEB2021	19FEB2021	BNT162b2 (30 µg)	12MAR2021	BNT162b2 (30 µg)
C4591001 1147 11471269	05DEC2020	Placebo	28DEC2020	Placebo	17FEB2021	24FEB2021	BNT162b2 (30 µg)		
C4591001 1147 11471270	05DEC2020	Placebo	28DEC2020	Placebo	17FEB2021	24FEB2021	BNT162b2 (30 µg)		
C4591001 1147 11471271	05DEC2020	Placebo	28DEC2020	Placebo	17FEB2021	24FEB2021	BNT162b2 (30 µg)		
C4591001 1150 11501131	20OCT2020	Placebo	09NOV2020	Placebo	16FEB2021	23FEB2021	BNT162b2 (30 µg)		
C4591001 1150 11501182	08DEC2020	Placebo	28DEC2020	Placebo	16FEB2021	25FEB2021	BNT162b2 (30 µg)		
C4591001 1150 11501242	23DEC2020	Placebo	15JAN2021	Placebo	02MAR2021	10MAR2021	BNT162b2 (30 µg)		
C4591001 1150 11501244	28DEC2020	Placebo	20JAN2021	Placebo	09FEB2021	17FEB2021	BNT162b2 (30 µg)	08MAR2021	BNT162b2 (30 µg)
C4591001 1152 11521604	02DEC2020	Placebo	21DEC2020	Placebo	03MAR2021	11MAR2021	BNT162b2 (30 µg)		
C4591001 1152 11521629	04DEC2020	Placebo	23DEC2020	Placebo	05JAN2021	05JAN2021	BNT162b2 (30 µg)	25JAN2021	BNT162b2 (30 µg)
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 02APR2021 (23:06) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_l003_plc_unb_ped									

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**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
12-15	C4591001 1006 10061272	1	22	06JAN2021	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/ANXIETY
		1	22	06JAN2021	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DEPRESSION
	C4591001 1007 10071409	1	10	31OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	exclusion #5 meet
	C4591001 1007 10071593	1	24	20JAN2021	VACCINATION	PROTOCOL DEVIATION	receipt of non-study COVID vaccine prior to study end
		1	47	12FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071622	1	22	20JAN2021	VACCINATION	OTHER	Participant had COVID-19 prior to second vaccine
	C4591001 1007 10071642	1	22	25JAN2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	clinical or microbiological diagnosis of COVID-19
	C4591001 1008 10081871	1	49	16FEB2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject tested positive for COVID 19
	C4591001 1008 10081884	1	50	18FEB2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject tested positive for COVID 19
	C4591001 1008 10081901	2	18	12FEB2021	VACCINATION	OTHER	the participant is willing/eligible to receive Vaccination 3

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Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001100910091229	1	21	09NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Covid positive between visit one and visit 2, exclusion #5
	C4591001100910091338	1	19	01JAN2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	exclusion #5
	C4591001100910091363	1	11	27DEC2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	has tested positive for COVID-19
	C4591001101610161316	1	17	01NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject with positive covid-19
	C4591001101610161379	1	30	05FEB2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject with positive covid test
	C4591001104410441344	2	11	08FEB2021	VACCINATION	OTHER	transitioning to open label
	C4591001105710571413			21DEC2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	DELAY CRITERIA MET
				21DEC2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	DELAY CRITERIA MET
	C4591001105710571420	2	45	24FEB2021	VACCINATION	WITHDRAWAL BY PARENT/GUARDIAN	mother stated she didn't want him to do it anymore
		2	45	24FEB2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	mother stated she didn't want him to do it anymore

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment^b
	C4591001106610661428	2	17	11FEB2021	VACCINATION	OTHER	subject unblinded for vax 3 per protocol
	C4591001107710771293			18DEC2020	SCREENING	OTHER	SUBJECT WAS RANDOMIZED THE SUBSEQUENTLY UNABLE TO TOLERATE BLOOD DRAW.
				18DEC2020	VACCINATION	REFUSED FURTHER STUDY PROCEDURES	REFUSED FURTHER STUDY PROCEDURES
	C4591001109110911414	1	14	22DEC2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Tested positive for Covid (exclusion 5)
	C4591001109110911451			04JAN2021	FOLLOW-UP	OTHER	Subject was rescreened under #1462. Subject randomized in error.
	C4591001112611261287	1	15	30DEC2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject did not receive 2nd vaccine due to Covid 19 disease.
	C4591001113911391235	2	19	15FEB2021	VACCINATION	OTHER	Crossed over to Visit 101
	C4591001113911391263	2	19	19FEB2021	VACCINATION	OTHER	Crossed-over
	C4591001114011401346			22DEC2020	SCREENING	OTHER	DISCONTINUED
				22DEC2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	SUBJECT TO BE DISCONTINUED DUE TO UNABLE TO OBTAIN SPECIMEN

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
16-25	C4591001114711471327	1	4	08JAN2021	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/PYREXIA
	C4591001115611561316	2	73	10MAR2021	VACCINATION	PROTOCOL DEVIATION	SUBJECT CAN NOT BE REACHED VIA PHONE. CERTIFIED LETTER SENT. SUBJECT CONTINUES TO COMPLETE eDIARY.
	C4591001115611561320	2	34	25JAN2021	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT AND FATHER STATED THAT THEY NO LONGER WISHED TO PARTICIPATE IN THE TRIAL.
	C4591001127012701237	1	20	26JAN2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	EC#55: Participant had a positive local COVID-19 test before Vx2, symptomatic with test
	C4591001100110011125	1	37	09SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Withdrew consent and decided not to continue in study.
		1	37	09SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient withdrew consent
	C4591001100510051238	2	65	06JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WAS UNBLINDED AND FOUND OUT HE RECEIVED PLACEBO. HE DECIDED TO WITHDRAW
	C4591001100510051341	1	2	22OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject tested COVID positive between visits 1 and 2
	C4591001100610061174	2	113	22FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Inclusion 2

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Age Group (Years)	Subject	Dose No.	Rel Day^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment^b
	C4591001 1007 10071556	2	29	26JAN2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion #12; received COVID vaccine outside of study
		2	29	26JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1008 10081480	2	115	04FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	site unable to make contact with subject despite numerous attempts
	C4591001 1009 10091235	2	107	25FEB2021	REPEAT SCREENING 1	OTHER	Visit 101 delayed due to recent vaccination
	C4591001 1009 10091257	1	10	05NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	positive for COVID-19
	C4591001 1009 10091286	2	13	04JAN2021	VACCINATION	OTHER	subject transitioned to open prior to visit 3
	C4591001 1013 10131395	2	45	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	ATTEMPTED TO CONTACT.
		2	45	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	UNABLE TO CONTACT SUBJECT AFTER MULTIPLE ATTEMPTS.
	C4591001 1013 10131592	2	31	11NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent from study.
		2	31	11NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	MOVED OUT OF STATE NO LONGER WANTED TO PARTICIPATE.

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
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Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001101310131683	2	129	10MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT DID NOT WISH TO CONTINUE IN STUDY.
	C4591001101310131740			15OCT2020	FOLLOW-UP	OTHER	randomized in error, needed to wait until course of antibiotics was done.
	C4591001101610161348	1	10	14NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject had positive pcr covid test
	C4591001101810181054	1	39	11SEP2020	VACCINATION	LOST TO FOLLOW-UP	patient returned to home country, did not respond to outreach, certified letter sent
		1	39	11SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject returned to home country, according to call to emergency contact
	C4591001101810181335	2	104	24FEB2021	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
		2	104	24FEB2021	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001102810281294	1	7	04NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	patient had positive covid test prior to V2
	C4591001103610361011	1	1	20AUG2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up
		1	1	20AUG2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
	C4591001103610361032	2	48	03NOV2020	VACCINATION	LOST TO FOLLOW-UP	unreachable

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Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		2	48	03NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	unreachable
	C4591001 1036 10361061	2	155	22FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow-up
	C4591001 1036 10361062	2	136	03FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject didn't return for Convalescent visit & multiple attempts to contact have been unsuccessful
	C4591001 1036 10361073	2	151	22FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow-up
	C4591001 1037 10371078	1	44	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	SITE ATTEMPTED CONTACT ON 22 SEP 30 SEP AND CERTIFIED LETTER SENT 8 OCT NO RESPONSE
		1	44	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT 8 OCT. PT DID NOT RESPOND
	C4591001 1039 10391093	2	137	08FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Contacted multiple times via phone and email, and was sent certified letter, all with no response
	C4591001 1039 10391244	1	13	23NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Patient tested positive for COVID-19.
	C4591001 1042 10421112	2	111	28DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrew consent
	C4591001 1044 10441287	1	19	29DEC2020	VACCINATION	OTHER	subject proceeded to open label prior to Vax2 in the blinded treatment phase.

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
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Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001104810481088	2	49	12NOV2020	VACCINATION	OTHER	out of state at time of visit 3
	C4591001105210521054	1	25	21SEP2020	VACCINATION	LOST TO FOLLOW-UP	n/a
		1	25	21SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up
	C4591001105210521064	1	25	24SEP2020	VACCINATION	LOST TO FOLLOW-UP	n/a
		1	25	24SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost of follow up
	C4591001105210521080	1	28	29SEP2020	VACCINATION	LOST TO FOLLOW-UP	lost of follow up
		1	28	29SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost of follow up
	C4591001105410541007	2	130	15JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	unblinding of subject occurred due to future non-study covid-19 vaccination
	C4591001105410541022	1	64	23OCT2020	VACCINATION	LOST TO FOLLOW-UP	Pt deemed LTFU by site.
		1	64	23OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Pt deemed LTFU by site.
	C4591001105410541165	2	47	24NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subj. did not show up for V3, despite sending certified letter and contacting pt via phone 3 times.
		2	47	24NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subj. did not show up for V3, despite sending certified letter and contacting pt via phone 3 times.

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Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1056 10561392	2	73	13JAN2021	VACCINATION	LOST TO FOLLOW-UP	Subject was discontinued from study after several unsuccessful TC and a Certified Letter.
		2	73	13JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was discontinued from study after several unsuccessful TC and a Certified Letter.
	C4591001 1056 10561511	2	103	12FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject informed us he no longer wanted to continue in the study.
	C4591001 1056 10561554	1	86	13JAN2021	VACCINATION	LOST TO FOLLOW-UP	Subject was discontinued from study after several unsuccessful TC and a Certified Letter.
		1	86	13JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was discontinued from study after several unsuccessful TC and a Certified Letter.
	C4591001 1056 10561592	2	81	18FEB2021	VACCINATION	LOST TO FOLLOW-UP	After many attempts to contact subject, Investigator decided to discontinue Pt. as a LTFU
		2	81	18FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	After many attempts to contact subject, Investigator decided to discontinue Pt. as a LTFU
	C4591001 1057 10571211			18SEP2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	subject was randomized but failed to meet entry criteria, no vaccine was given
	C4591001 1057 10571216	2	30	10NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	MOVED TO (b) (6)
		2	30	10NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	MOVED TO (b) (6)

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1057 10571230	2	56	23DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	PERSONAL REASONS
		2	56	23DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	PERSONAL REASONS
	C4591001 1057 10571248	1	36	30OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject refused to return for Visit 2, withdrew consent, No adverse events reported
		1	36	30OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent from further study participation
	C4591001 1057 10571319	2	47	28DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrew consent due to transportation issues
		2	47	28DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrew consent due to transportation issues
	C4591001 1066 10661396	1	22	22DEC2020	VACCINATION	OTHER	unblinded to assess eligibility for vaccination
	C4591001 1073 10731038	1	37	10SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject was Discontinue
		1	37	10SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Discontinue
	C4591001 1073 10731067	2	157	05FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdrew Consent
	C4591001 1079 10791253	1	67	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	patient unresponsive

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	67	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	patient unresponsive
	C4591001 1080 10801019	2	155	01FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Patient received vaccine outside of the study.
	C4591001 1080 10801055	2	105	21DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Patient was vaccinated for COVID by her employer prior to being unblinded
	C4591001 1084 10841512	2	119	09MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject will not be available for follow-up appointments.
	C4591001 1085 10851081	2	87	30NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject no longer interested in the study.
		2	87	30NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Site received call call from patient stating she was no longer interested in the study.
	C4591001 1085 10851244	2	97	30DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Received vaccine elsewhere
	C4591001 1087 10871089	1	19	04SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criteria #5
	C4591001 1087 10871279	2	156	23FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject is unwilling to return for vaccine if in the placebo group.
	C4591001 1087 10871354	1	10	17SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/MYALGIA
		1	10	17SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/MYALGIA

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1087 10871356	1	54	31OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up.
		1	54	31OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up.
	C4591001 1087 10871363	2	56	23NOV2020	VACCINATION	LOST TO FOLLOW-UP	lost to follow up
		2	56	23NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up.
	C4591001 1089 10891179	2	157	18FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject moved, withdrew consent
	C4591001 1090 10901328	2	63	25NOV2020	VACCINATION	LOST TO FOLLOW-UP	pt did not come for V3 and was unresponsive to calls and certified letter
		2	63	25NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Pt did not come for V3 and not responsive to calls or certified letter
	C4591001 1090 10901517	2	49	29DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject requested to be unblinded before eligibility
	C4591001 1091 10911122	2	169	16FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received moderna vaccine
	C4591001 1092 10921055	2	138	29JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is lost to follow-up
	C4591001 1092 10921128			01SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt withdrew consent due to anxiety of having blood drawn

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1093 10931055			31AUG2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	UNABLE TO OBTAIN BLOOD FROM SUBJECT.
	C4591001 1093 10931058	1	25	18SEP2020	VACCINATION	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY
		1	77	09NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was lost to follow up./EXPOSURE DURING PREGNANCY
	C4591001 1093 10931072	1	81	14NOV2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT WAS SENT A CERTIFIED LETTER AND WAS UNABLE TO BE CONTACTED MULTIPLE TIMES.
		1	81	14NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT WAS SENT A CERTIFIED LETTER AND WAS UNABLE TO BE CONTACTED MULTIPLE TIMES.
	C4591001 1094 10941169	2	120	23FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received the non study covid 19 vaccine before being discontinued or withdrawing from study
	C4591001 1095 10951056	1	35	08SEP2020	VACCINATION	OTHER	not able to meet study requirements due to work schedule
		1	35	08SEP2020	FOLLOW-UP	OTHER	Participant not able to continue in study at this time. Participant did not withdraw consent
	C4591001 1095 10951271	2	1	28OCT2020	VACCINATION	LOST TO FOLLOW-UP	certified letter sent
		2	1	28OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	certified letter sent

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment^b
	C4591001 1096 10961031	1	22	04SEP2020	VACCINATION	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY
	C4591001 1096 10961081	1	54	12OCT2020	VACCINATION	LOST TO FOLLOW-UP	LTFU, unresponsive to contact attempts
		1	54	12OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	site unable to contact subject after multiple attempts and certified letter sent
	C4591001 1096 10961141	1	22	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criteria #5
	C4591001 1096 10961321	1	22	03OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject met exclusion #1 on visit 2 (suicidal ideation) so no vaccine was administered
	C4591001 1096 10961388	1	21	29OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject was diagnosed with COVID between vaccination one and vaccination two
	C4591001 1098 10981200	1	46	05NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject called multiple times and certified letter was sent. No response from subject
		1	46	05NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject called multiple times and certified letter was sent. No response from subject.
	C4591001 1098 10981243	2	139	08MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Discontinued
	C4591001 1098 10981244	2	84	12JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject has been discontinued due to lost of followup.

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1109 11091030	2	37	23SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT CALLED TO WITHDRAW FROM TRIAL DUE TO TRANSPORTATION ISSUES AS WELL AS BEING TOO BUSY.
		2	37	23SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT CALLED TO WITHDRAW FROM TRIAL DUE TO TRANSPORTATION ISSUES AS WELL AS BEING TOO BUSY.
	C4591001 1109 11091059	1	40	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RETURNED PHONE CALLS OR RESPOND TO CERTIFIED LETTER.
		1	40	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RETURNED PHONE CALLS OR RESPOND TO CERTIFIED LETTER.
	C4591001 1109 11091335	1	43	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO MULTIPLE CALLS AND CERTIFIED LETTER SENT TO HER
		1	43	07OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO MULTIPLE CALLS AND CERTIFIED LETTER SENT TO HER
	C4591001 1109 11091515	1	30	14OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject never returned for visit, responded to call or certified letter sent.
		1	30	14OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject never returned for visit, responded to call or certified letter sent.
	C4591001 1110 11101010	2	63	22OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not comply with inclusion criteria #2.
		2	63	22OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not comply with inclusion criteria #2.
	C4591001 1110 11101038	1	35	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject was contact over the phone 3 times and a certified letter was sent. Subject never reply.

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment^b
		1	35	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow is status, subject has been withdrawn from trial.
	C4591001 1110 11101039	1	35	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	subject failed to contact site after many calls and certified letter.
		1	35	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not respond to many phones calls from site and did not respond to certified letter fromi
	C4591001 1110 11101085	1	58	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject was tried to contact by phone, text, email and certified letter several times.
		1	58	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	we did 4 phone call attempts, 1 text message, 1 email and a certified letter.
	C4591001 1110 11101110	1	22	08SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		1	22	08SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1110 11101156	1	96	01DEC2020	VACCINATION	LOST TO FOLLOW-UP	Subject was attempt to contact by 2 text messages, 1 certified letter, 1 email and 8 phone call.
		1	96	01DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was attempt to contact by 2 text messages, 1 certified letter, 1 email and 8 phone call.
	C4591001 1110 11101380	2	38	29JAN2021	VACCINATION	WITHDRAWAL BY PARENT/GUARDIAN	Parent discontinue subject because he states subject is too busy with school.
		2	38	29JAN2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Parent discontinued subject because he states subject is too busy with school.

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1112 11121058	1	22	25AUG2020	VACCINATION	OTHER	(b) (6)
		1	22	25AUG2020	FOLLOW-UP	OTHER	(b) (6)
	C4591001 1112 11121229			04SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject left clinic after randomization and prior to vaccination
	C4591001 1116 11161292	1	52	14NOV2020	VACCINATION	LOST TO FOLLOW-UP	Contact attempts 16OCT 22OCT 23OCT 3NOV 4NOV 9NOV 10NOV
		1	52	14NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Contact attempts 16OCT 22OCT 23OCT 3NOV 4NOV 9NOV 10NOV
	C4591001 1116 11161322	2	55	07DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW FROM STUDY
		2	55	07DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1117 11171138	2	31	17DEC2020	VACCINATION	PROTOCOL DEVIATION	COULD NOT GET PARTICIPANT SCHEDULED FOR V3
	C4591001 1120 11201038			29OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdraw consent
	C4591001 1120 11201240	2	163	20FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject is moving out of town

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1121 11211009	2	40	22OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew due to busy schedule.
		2	40	22OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent due to busy schedule. Does not want to be FU
	C4591001 1121 11211010	2	180	11MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject asked to be withdrawn then hung up. Attempted to reach her again, she answered then hung up.
	C4591001 1121 11211067	2	100	30DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent to receive vaccine at work.
	C4591001 1122 11221026			11SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/PRESYNCOPE
				11SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/VOMITING
	C4591001 1123 11231027			04AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent after randomization prior to vaccination.
	C4591001 1123 11231051	2	43	08OCT2020	VACCINATION	OTHER	moved to (b) (6)
		2	43	08OCT2020	FOLLOW-UP	OTHER	Moved to (b) (6)
	C4591001 1123 11231069	2	190	09MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent. Left voicemail with the patient.
	C4591001 1123 11231154	1	73	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	no response from subject after certified letter

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	73	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	no response from subject after certified letter
	C4591001 1124 11241038	2	106	16DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew to receive Covid-19 at workplace
	C4591001 1124 11241049	1	26	11SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject not responding to any phone calls, certified letter sent
		1	26	11SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject not responding to any phone calls, certified letter sent
	C4591001 1124 11241141	2	64	24NOV2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up after multiple calls and certified letter sent
		2	64	24NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
	C4591001 1125 11251059	2	76	24NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject missed appt and diary entries. Multiple contact attempts with subject were not returned.
		2	76	24NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Patient deemed lost to follow
	C4591001 1125 11251142	2	154	24FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	moved from the area no longer able to make visits
	C4591001 1125 11251238	1	12	02NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Patient tested positive for Covid-19, EXC #5
	C4591001 1125 11251243	1	2	09DEC2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/HEADACHE
		1	2	09DEC2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/INJECTION SITE PAIN

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment^b
	C4591001 1127 11271078	2	137	11JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to followup
	C4591001 1127 11271099	1	22	09SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject tested positive and symptoms for COVID
	C4591001 1128 11281177	2	113	19JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY
	C4591001 1129 11291048			04AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	screen fail
				04AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	violation exclusion criteria 2.f. immunocompromised. randomized but not dosed
	C4591001 1129 11291260	2	44	27JAN2021	OPEN LABEL TREATMENT	ADVERSE EVENT	ADVERSE EVENT/ANAPHYLACTOID REACTION
	C4591001 1133 11331037	1	27	26AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
		1	27	26AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331047	2	8	31AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject does not want to continue in the study
		2	8	31AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment^b
	C4591001 1133 11331135	2	166	16FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent after unblinding. Requested time to think about it. Made decision on 16/FEB
	C4591001 1133 11331207	1	43	30SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
		1	43	30SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1133 11331480	2	127	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT 08/FEB/2021
	C4591001 1133 11331647	2	31	23DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject leaving and does not want to come in for any future visits.
	C4591001 1135 11351199	1	39	01OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up, certified letter sent to patient.
		1	39	01OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject lost to follow-up, certified letter sent
	C4591001 1135 11351428	1	27	19OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject contact attempted several times and certified letter was sent on 19OCT2020
		1	27	19OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject contact attempted several times and certified letter was sent on 19OCT2020
	C4591001 1141 11411077	2	118	04JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew to receive EUA vaccine outside of the study.

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment^b
	C4591001 1146 11461140	2	178	13MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew
	C4591001 1149 11491332	2	23	03DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject moved out of State and will not be able to committee to follow-ups
		2	23	03DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject moved out of state and withdrew from study.
	C4591001 1152 11521030	1	22	02SEP2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1152 11521208	2	81	04DEC2020	VACCINATION	PROTOCOL DEVIATION	Non-compliant with attending study visits.
		2	115	07JAN2021	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1156 11561015	1	39	28SEP2020	VACCINATION	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY
	C4591001 1157 11571077	2	30	14OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject W/C due to moving
		2	30	14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Voluntary withdrawal not due to an AE or SAE
	C4591001 1161 11611006	1	111	18NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject chose to withdraw from study
		1	111	18NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject chose to withdraw from study.

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1161 11611007	1	103	10NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	No longer meets an eligibility criteria per exclusion #5. VAX2 is not given but FUP will be complete
		1	146	23DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	unable to contact, certified letter was sent and no response.
	C4591001 1161 11611008	1	103	10NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1161 11611010	1	134	11DEC2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
		1	216	03MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject stated he did not want to continue in study.
	C4591001 1161 11611018	1	115	23NOV2020	VACCINATION	LOST TO FOLLOW-UP	multiple calls and cert. letter sent. No response from subject.
		1	115	23NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	multiple calls and certified letter sent. no response from subject
	C4591001 1161 11611023	1	72	13OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject had several contact attempts by site along with certified letter. Unable to contact subject.
		1	72	13OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	cert. letter sent and signed by subject. unable to contact and subject has not called site.
	C4591001 1161 11611024	1	107	17NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	unable to contact subject. certified letter returned, no response from subject
		1	107	17NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject did not want to continue in study

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1161 11611028	2	83	02FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	3 phone call attempts and certified letter sent with no response.
	C4591001 1162 11621005	1	32	31AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject prematurely withdrew from study.
		1	32	31AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject prematurely withdrawn from study.
	C4591001 1162 11621044	2	194	09MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow-up
	C4591001 1162 11621074	2	73	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	subject LTFU after multiple contact attempts.
		2	73	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject LTFU after multiple contact attempts.
	C4591001 1162 11621080	2	64	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU
		2	64	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU
	C4591001 1162 11621310	1	60	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU
		1	60	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU
	C4591001 1162 11621374	1	54	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU
		1	54	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU after many contact attempts.

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1162 11621434	2	1	19OCT2020	VACCINATION	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
		2	1	19OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
	C4591001 1167 11671111	1	38	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject is lost to follow up tried multiple calls and certified letter
		1	38	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	no answer after multiple calls and sent certified letter
	C4591001 1167 11671132	2	98	28DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	subject received out of study covid vaccine
	C4591001 1168 11681212	2	1	15OCT2020	VACCINATION	OTHER	The visit was missed due to pt working out of state. The subject will continue on in the study.
	C4591001 1168 11681221	2	54	21DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject chose to no longer participate, complete study procedures, or respond to follow up requests.
		2	54	21DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject chose to no longer participate, complete study procedures, or respond to follow up requests.
	C4591001 1168 11681227	1	37	17NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTF after several attempts to contact and certified letter sent
		1	37	17NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTF after several attempts to contact and certified letter sent
	C4591001 1169 11691014	2	104	04JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject did not want to wait 28 days to receive study vaccine after receiving HPV vaccine 12/21/20

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1169 11691060	2	36	17NOV2020	VACCINATION	LOST TO FOLLOW-UP	Lost to Follow Up
		2	36	17NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1170 11701048	2	166	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1170 11701076	2	163	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1170 11701089	2	161	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1170 11701146	2	168	09MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up subject contacted multiple times for scheduling
	C4591001 1170 11701311	1	33	16OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject contacted multiple times, never responded.
		1	33	16OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow-up subjects subject didnt come for visit.
	C4591001 1170 11701487	2	99	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1170 11701494	2	99	23FEB2021	VACCINATION	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
		2	99	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1195 11951029	2	78	20JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the upcoming visits is to stressful for the patient at this time.
	C4591001 1195 11951061	1	21	06NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	patient withdrawal consent. she is afraid about the second vaccination
		1	21	06NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient is afraid for the second vaccination
	C4591001 1218 12181011	2	99	02MAR2021	VACCINATION	WITHDRAWAL BY SUBJECT	We made contact with participant 02MAR2021, she was informed of her vaccine status but withdrew.
		2	99	02MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Participant requested to withdraw from study as they have moved out of state
	C4591001 1218 12181050	1	21	23DEC2020	VACCINATION	OTHER	Subject proceeded to open label prior to Vax2 in blinded treatment phase
	C4591001 1220 12201036	1	44	17DEC2020	VACCINATION	LOST TO FOLLOW-UP	unable to contact participant due to multiple attempts
		1	44	17DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	Unable to contact participant after multiple attempts
	C4591001 1221 12211036	2	52	27JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew from study
	C4591001 1224 12241009	1	37	18SEP2020	VACCINATION	LOST TO FOLLOW-UP	PT failed to attend V2; site attempted contact via phone and certified letter
		1	37	18SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	PT failed to return for V2; site attempted contact via phone and certified letter

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment^b
	C4591001 1224 12241167	1	27	16DEC2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criteria 5
	C4591001 1224 12241169	2	23	06JAN2021	VACCINATION	OTHER	subject proceeded to open label prior to V3 in the blinded Rx phase
	C4591001 1224 12241170			24NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject chose to discontinue from trial
	C4591001 1224 12241175	1	17	16DEC2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criteria 5
	C4591001 1226 12262189	1	14	27OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1230 12301065	2	97	02MAR2021	VACCINATION	WITHDRAWAL BY SUBJECT	Participant translocated and will no longer be able to attend site visits
		2	97	02MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Participant confirmed that he has translocated. Attending additional visits will be difficult.
	C4591001 1231 12311031	1	37	15SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311062	2	165	12FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	After multiple contact attempts, a registered letter is sent. Subject receives it on 3FEB2021

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1231 12311088	1	48	28SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311191	1	32	14SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311431	1	27	10SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject is afraid of exposure to COVID-19 in next study visits
		1	27	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	you fear going to a health institution and that this will expose you to be reinfected by SARS-COV2
	C4591001 1231 12311593	2	147	01FEB2021	VACCINATION	LOST TO FOLLOW-UP	After multiple unanswered phone calls, a certified letter was sent and it was never responded.
		2	147	01FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Volunteer with loss of follow-up
	C4591001 1231 12311641	1	29	13SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311656	1	40	24SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312326	1	34	21SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312365	1	28	15SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
		1	56	13OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject decided to withdraw consent due to lack of time
	C4591001123112312403	1	24	11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The patient does not want to take the second dose.
	C4591001123112312451	1	23	11SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Participants who are willing and able to comply with all scheduled visits, vaccination plan, lab...
	C4591001123112312528	2	123	11JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	On JAN-9-2021, subject received the Gam-COVID-Vac vaccine (trade name Sputnik V).
	C4591001123112312594	1	77	04NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Stop participating for personal reasons
		1	77	04NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdraws his consent for personal reasons
	C4591001123112312916	1	20	09SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19.
	C4591001123112313443			23AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	randomized, no vaccinated
	C4591001123112313467	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not agree to be vaccinated a second time,but will continue in the study
	C4591001123112313498	1	25	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not agree to be vaccinated a second time,but will continue in the study

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment^b
	C4591001 1231 12313519	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Did not accept to receive second dose but accept continue with the rest of study procedures
	C4591001 1231 12313546	1	26	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject did not receive the second vaccination but continued otherwise with study procedures
	C4591001 1231 12313622	1	24	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Healthy participants eligible for inclusion in the study and Previous diagnosis of COVID-19
	C4591001 1231 12313758	1	44	06OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313981	2	45	29OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The decision to stop participating must be a move to the province of Santiago del Estero.
		2	45	29OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The decision to stop participating must be a move to the province of Santiago del Estero.
	C4591001 1231 12314492	1	20	15SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
		1	142	15JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	12 telephone contact attempts. 2 email contact attempts. 1 certified letter sent.
	C4591001 1231 12315357	1	13	10SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject does not specify the reasons for withdrawing from the study
		1	13	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject does not specify the reasons for withdrawing from the study

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment^b
	C4591001 1232 12321015	1	21	02SEP2020	VACCINATION	LOST TO FOLLOW-UP	patient is labeled a "no show"
		1	21	02SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	patient labeled as a "no show"
	C4591001 1232 12321142	1	24	23SEP2020	VACCINATION	OTHER	re-joined trial in the revaccination open label portion
	C4591001 1232 12321210	2	67	06DEC2020	VACCINATION	LOST TO FOLLOW-UP	multiple attempts to contact patient, phone is no longer in service
		2	67	06DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts to contact patient, phone is no longer in service
	C4591001 1232 12321244	1	1	11SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return the sites calls
		1	1	11SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is not returning any of the sites phone calls. Will not be rejoining.
	C4591001 1232 12321412	1	1	27OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from the site
		1	1	27OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from the site
	C4591001 1232 12321429	1	1	28OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V2 and has not returned calls from the site
		1	1	28OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V2 and has not returned calls from the site

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1235 12351187	1	9	24OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	meets exclusion #5
	C4591001 1247 12471107	2	29	17NOV2020	VACCINATION	LOST TO FOLLOW-UP	Pt did not arrive for Visit 3. After multiple attempts by site staff, pt still did not arrive for V3
	C4591001 1247 12471121	2	10	30OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Patient withdrew after motorcycle accident (Undisclosed medical condition)
		2	10	30OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient withdrew after motorcycle accident (Undisclosed medical condition)
	C4591001 1248 12481025			29AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdrew Consent
	C4591001 1248 12481046	1	66	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	Missed V2 on 20Sep2020; site has been unable to contact subject despite multiple calls.
		1	66	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Please see EOT page
	C4591001 1248 12481110	1	59	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject was no show for V2; unable to contact subject.
		1	59	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was no show for V2; unable to contact subject.
	C4591001 1248 12481138	2	125	02FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject said she no longer wishes to participate in the study. No reason given.

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 1248 12481206	2	1	09OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up
		2	1	09OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1254 12541142	1	26	07OCT2020	VACCINATION	PREGNANCY	PREGNANCY/MATERNAL EXPOSURE DURING PREGNANCY
	C4591001 1258 12581069	2	55	04JAN2021	VACCINATION	WITHDRAWAL BY SUBJECT	subject moved and withdrew consent
		2	55	04JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject moved and withdrew consent
	C4591001 1269 12691047	2	126	18JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject discontinued her participation
	C4591001 1270 12701175	2	66	24FEB2021	VACCINATION	WITHDRAWAL BY SUBJECT	Per LAR/father, request to drop participant, non-compliant with study activities
		2	66	24FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Per LAR/father request to drop participant as has been non-compliant with study activities
	C4591001 1270 12701176	2	66	24FEB2021	VACCINATION	WITHDRAWAL BY SUBJECT	Per LAR/father, request to drop participant, non-compliant with study activities
		2	66	24FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Per LAR/father, request to drop participant as participant is non-compliant with study activities
	C4591001 4444 44441329	2	81	31DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal issues.

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Withdrawal Date	Study Phase	Withdrawal Reason	Comment ^b
	C4591001 4444 44442006	2	140	02MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is for personal reasons
	C4591001 4444 44442081	2	145	08MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision is due to "the little collaboration of Pfizer with the Argentine State."
	C4591001 4444 44442263	1	24	20OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Will not be able to continue in the trial since she has had to travel abroad for personal reasons
		1	24	20OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Will not be able to continue in the trial since she has had to travel abroad for personal reasons
<p>a. Relative day (Rel Day) = date of withdrawal - date of last vaccination + 1. For a withdrawal that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.</p> <p>b. MedDRA (v23.1) coding dictionary applied.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 27MAR2021 (00:55) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adds_l001_withdraw_ped</p>							

16.2.2.1 Listing of Important Protocol Deviations – Subjects 12 Through 25 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Age Group/Subject (Number of Deviations if >1)
Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	14	16-25 Years/C4591001 1007 10071082 (2)
			16-25 Years/C4591001 1007 10071556
			12-15 Years/C4591001 1007 10071593
			16-25 Years/C4591001 1080 10801019
			16-25 Years/C4591001 1080 10801055
			16-25 Years/C4591001 1085 10851244
			16-25 Years/C4591001 1091 10911122
			16-25 Years/C4591001 1094 10941169
			16-25 Years/C4591001 1121 11211067
			16-25 Years/C4591001 1128 11281177
			16-25 Years/C4591001 1167 11671132
			16-25 Years/C4591001 1169 11691014
			16-25 Years/C4591001 1231 12312528
			16-25 Years/C4591001 1269 12691047

16.2.2.1 Listing of Important Protocol Deviations – Subjects 12 Through 25 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Age Group/Subject (Number of Deviations if >1)
Inclusion/exclusion	Subject received systemic corticosteroids (≥ 20 mg/day of prednisone or equivalent) for ≥ 14 days is prohibited from 28 days prior to enrollment to specified visits/cohorts per protocol.	2	12-15 Years/C4591001 1126 11261254 16-25 Years/C4591001 1247 12471244
	Participant failed to meet inclusion criterion #03 (Healthy participants who are determined by medical history, physical examination and clinical judgement of the investigator to be eligible for inclusion in the study)	3	16-25 Years/C4591001 1120 11201038 16-25 Years/C4591001 1161 11611023 16-25 Years/C4591001 1231 12311088
	Participant met exclusion criterion #01 (participant having other medical or psychiatric condition)	3	16-25 Years/C4591001 1006 10061246 12-15 Years/C4591001 1006 10061272 12-15 Years/C4591001 1009 10091320
	Participant met exclusion criterion #05 (previous clinical or microbiological diagnosis of COVID-19)	1	16-25 Years/C4591001 1231 12311191
	Participant met exclusion criterion #11 (women who are pregnant or breastfeeding)	4	16-25 Years/C4591001 1133 11331207 16-25 Years/C4591001 1156 11561015 16-25 Years/C4591001 1161 11611016 16-25 Years/C4591001 1254 12541142

16.2.2.1 Listing of Important Protocol Deviations – Subjects 12 Through 25 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Age Group/Subject (Number of Deviations if >1)
Investigational product Blind compromised	Participant met exclusion criterion #22 (investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members)	3	16-25 Years/C4591001 1112 11121058
			16-25 Years/C4591001 1161 11611008
			16-25 Years/C4591001 1161 11611018
	Dosing/administration error, subject did not receive correct dose of vaccine	1	16-25 Years/C4591001 1096 10961195
			16-25 Years/C4591001 1068 10681002
		16	16-25 Years/C4591001 1068 10681010
			16-25 Years/C4591001 1068 10681018
			16-25 Years/C4591001 1068 10681037
			16-25 Years/C4591001 1068 10681047
			16-25 Years/C4591001 1141 11411065
			16-25 Years/C4591001 1141 11411139
			16-25 Years/C4591001 1231 12313467
			16-25 Years/C4591001 1231 12313498

16.2.2.1 Listing of Important Protocol Deviations – Subjects 12 Through 25 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Age Group/Subject (Number of Deviations if >1)
			16-25 Years/C4591001 1231 12313505
			16-25 Years/C4591001 1231 12313515
			16-25 Years/C4591001 1231 12313519
			16-25 Years/C4591001 1231 12313533
			16-25 Years/C4591001 1231 12313542
			16-25 Years/C4591001 1231 12313546
			16-25 Years/C4591001 1231 12313553
	IP administered that was deemed not suitable for use by Almac	4	16-25 Years/C4591001 1024 10241091
			16-25 Years/C4591001 1044 10441034
			16-25 Years/C4591001 1096 10961027
			16-25 Years/C4591001 1096 10961245
	Other IP deviation	3	16-25 Years/C4591001 1096 10961195
			16-25 Years/C4591001 1126 11261053
			16-25 Years/C4591001 1161 11611015

16.2.2.1 Listing of Important Protocol Deviations – Subjects 12 Through 25 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Age Group/Subject (Number of Deviations if >1)
Other	Subject was vaccinated despite being ineligible	1	16-25 Years/C4591001 1092 10921158
	Subject was vaccinated despite meeting temporary delay criterion #4 (receiving short-term (<14 days) systemic corticosteroids, IP administration should be delayed until systemic corticosteroid use has been discontinued for at least 28 days.	2	16-25 Years/C4591001 1028 10281294
			16-25 Years/C4591001 1247 12471244
	Efficacy data considered potentially unreliable due to lack of PI oversight identified as significant quality event	8	16-25 Years/C4591001 1161 11611007
			16-25 Years/C4591001 1161 11611008
			16-25 Years/C4591001 1161 11611009
			16-25 Years/C4591001 1161 11611010
			16-25 Years/C4591001 1161 11611023
			16-25 Years/C4591001 1161 11611024
			16-25 Years/C4591001 1161 11611026
			16-25 Years/C4591001 1161 11611028
	Safety and efficacy data considered potentially unreliable due to lack of PI oversight identified as significant quality event.	5	16-25 Years/C4591001 1161 11611006
			16-25 Years/C4591001 1161 11611015

16.2.2.1 Listing of Important Protocol Deviations – Subjects 12 Through 25 Years of Age			
Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Age Group/Subject (Number of Deviations if >1)
Procedures/tests	Subject had a vaccination diary activated, but was not part of the reactogenicity subset	2	16-25 Years/C4591001 1161 11611016
			16-25 Years/C4591001 1161 11611018
			16-25 Years/C4591001 1161 11611019
			16-25 Years/C4591001 1219 12191004
			16-25 Years/C4591001 1235 12351153
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: advv Table Generation: 27MAR2021 (01:37) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/addv_l001_pd_ped			

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
12-15	C4591001 1006 10061212	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1006 10061220	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1006 10061227	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1006 10061248	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1006 10061261	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1006 10061280	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1006 10061282	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1007 10071467	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1007 10071471	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1007 10071523	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1007 10071574	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1008 10081764	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1008 10081800	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1009 10091221	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1009 10091265	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1009 10091280	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1009 10091281	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1009 10091288	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1009 10091354	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131822	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131828	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131841	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131850	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131855	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1016 10161334	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1016 10161338	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1016 10161356	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1039 10391269	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1044 10441276	Dose 2 evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1044 10441295	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1057 10571378	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1057 10571396	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not receive Dose 2 within 19-42 days after Dose 1; did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1057 10571399	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1057 10571400	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1057 10571409	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1057 10571412	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1066 10661408	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1066 10661417	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1077 10771274	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1077 10771288	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1091 10911413	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231431	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231432	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231438	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231439	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231440	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231441	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231448	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1124 11241249	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1126 11261269	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1126 11261277	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1131 11311275	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1139 11391151	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1139 11391156	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1139 11391170	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1140 11401336	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1140 11401337	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1142 11421319	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1142 11421330	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1142 11421343	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1147 11471274	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1150 11501119	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1150 11501129	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521625	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521640	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521641	Dose 2 all- available	Did not receive Dose 2.
		Dose 2 evaluable	Did not receive 2 doses of the vaccine to which they were randomly assigned.
	C4591001 1152 11521645	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521656	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1152 11521657	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521661	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521667	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521679	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521683	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521684	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521686	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521689	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521697	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1156 11561257	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1156 11561304	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1156 11561311	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1156 11561321	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1156 11561324	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1235 12351246	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1270 12701177	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1270 12701187	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
16-25	C4591001 1006 10061137	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1006 10061159	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1007 10071434	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1007 10071447	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1007 10071454	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1007 10071473	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1008 10081743	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1009 10091210	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1009 10091235	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1011 10111213	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131059	Dose 2 evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1013 10131276	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131653	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131763	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131817	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1013 10131829	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1013 10131834	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not receive Dose 2 within 19-42 days after Dose 1; did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1015 10151150	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1018 10181032	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1046 10461346	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1047 10471275	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1047 10471306	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1056 10561171	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1056 10561392	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1057 10571217	Dose 2 evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1057 10571366	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1057 10571368	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1068 10681119	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1079 10791162	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not receive Dose 2 within 19-42 days after Dose 1; did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1080 10801055	Dose 2 evaluable	Had important protocol deviation(s) as determined by the clinician.
	C4591001 1080 10801179	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1082 10821036	Dose 2 evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1084 10841423	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1085 10851373	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1087 10871565	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1088 10881200	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1090 10901328	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1091 10911389	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1091 10911391	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1092 10921146	Dose 2 evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1093 10931174	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1093 10931203	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1095 10951271	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1095 10951310	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1096 10961032	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1096 10961196	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1096 10961392	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1098 10981177	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1109 11091391	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not receive Dose 2 within 19-42 days after Dose 1; did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1109 11091532	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1111 11111183	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1112 11121260	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1114 11141021	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1116 11161320	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1116 11161322	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1120 11201337	Dose 2 evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1123 11231416	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231417	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231429	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1123 11231430	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1125 11251240	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1126 11261231	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1126 11261234	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1131 11311064	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1131 11311268	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1133 11331609	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1135 11351239	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1135 11351323	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1135 11351461	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1135 11351492	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1135 11351497	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1135 11351556	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1139 11391132	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1140 11401316	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1141 11411006	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1141 11411269	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1142 11421338	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1147 11471260	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1149 11491079	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1149 11491302	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1150 11501016	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1150 11501188	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521115	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521451	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521464	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1152 11521632	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1156 11561203	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1156 11561288	Dose 2 evaluable Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1156 11561329	Dose 2 evaluable Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1162 11621479	Dose 2 evaluable Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1168 11681069	Dose 2 evaluable Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1170 11701089	Dose 2 evaluable Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1170 11701392	Dose 2 evaluable Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1170 11701419	Dose 2 evaluable Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1171 11711211	Dose 2 evaluable Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2. Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1171 11711221	Dose 2 evaluable	Did not receive Dose 2 within 19-42 days after Dose 1.
	C4591001 1177 11771540	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1204 12041144	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1204 12041275	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1218 12181047	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1220 12201015	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1221 12211036	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1224 12241183	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1224 12241187	Dose 2 all- available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
	C4591001 1232 12321302	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1235 12351014	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1235 12351230	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1254 12541121	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1254 12541178	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1258 12581069	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1264 12641095	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1270 12701195	Dose 2 all-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

**16.2.3.1.1 Listing of Subjects Excluded From Immunogenicity Populations –
Subjects 12 Through 25 Years of Age (Immunogenicity Subset)**

Age Group (Years)	Subject	Population	Reason for Exclusion
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 28MAR2021 (12:59) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_1001_excl_ped_eval			

16.2.3.2.1 Listing of Subjects Excluded From Safety Population – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	Reason for Exclusion
12-15	C4591001 1057 10571413	Subject did not receive study vaccine.
	C4591001 1077 10771293	Subject did not receive study vaccine.
	C4591001 1091 10911451	Subject did not receive study vaccine.
	C4591001 1140 11401346	Subject did not receive study vaccine.
16-25	C4591001 1013 10131740	Subject did not receive study vaccine.
	C4591001 1057 10571211	Subject did not receive study vaccine.
	C4591001 1092 10921128	Subject did not receive study vaccine.
	C4591001 1093 10931055	Subject did not receive study vaccine.
	C4591001 1112 11121229	Subject did not receive study vaccine.
	C4591001 1120 11201038	Subject did not receive study vaccine.
	C4591001 1122 11221026	Subject did not receive study vaccine.
	C4591001 1123 11231027	Subject did not receive study vaccine.
	C4591001 1129 11291048	Subject did not receive study vaccine.
	C4591001 1161 11611006	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611015	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611016	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611018	Unreliable data due to lack of PI oversight.
	C4591001 1161 11611019	Unreliable data due to lack of PI oversight.
	C4591001 1224 12241170	Subject did not receive study vaccine.
	C4591001 1231 12313443	Subject did not receive study vaccine.
	C4591001 1231 12313527	Subject did not receive study vaccine.
	C4591001 1248 12481025	Subject did not receive study vaccine.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_l001_excl_ped_saf_all

16.2.5.1.1 Listing of Subjects Who Received Vaccine Not as Randomized – Subjects 12 Through 25 Years of Age

Vaccine Group (as Randomized)	Age Group (Years)	Subject	Randomization Date	Vaccination Date	Dose No.	Vaccine Received
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No subject meets the reporting criteria.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:45)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_l001_ped_rand_notvax

16.2.5.2.1 Listing of Medication Errors – Subjects 12 Through 25 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
16-25	C4591001101110111215	1	19OCT2020	Product administration error	DOSE NOT CHANGED	N	N	19OCT2020	N	N
	C4591001102410241091	1	28AUG2020	Product storage error	DOSE NOT CHANGED	N	N	28AUG2020	N	N
	C4591001104410441034	1	26AUG2020	Product storage error	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001106810681002	1	18AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	18AUG2020	N	N
	C4591001106810681010	1	19AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	19AUG2020	N	N
	C4591001106810681018	1	20AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001106810681037	1	24AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	24AUG2020	N	N
	C4591001106810681047	1	26AUG2020	Incorrect dosage administered	DOSE NOT CHANGED	N	N	26AUG2020	N	N
	C4591001107910791170	3	25FEB2021	Product administration error	DOSE NOT CHANGED	N	N	25FEB2021	N	N

16.2.5.2.1 Listing of Medication Errors – Subjects 12 Through 25 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1096 10961027	3	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001 1096 10961195	2	21SEP2020	Product administration error	DOSE NOT CHANGED	N	N	21SEP2020	N	N
	C4591001 1096 10961245	4	26FEB2021	Product storage error	DOSE NOT CHANGED	N	N	26FEB2021	N	N
	C4591001 1126 11261053	1	20AUG2020	Expired product administered	DOSE NOT CHANGED	N	N	20AUG2020	N	N
	C4591001 1141 11411065	1	12AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	12AUG2020	N	N
	C4591001 1141 11411139	1	27AUG2020	Incorrect dose administered	DOSE NOT CHANGED	N	N	27AUG2020	N	N
	C4591001 1146 11461338	2	13NOV2020	Product administration error	DOSE NOT CHANGED	N	N	13NOV2020	N	N
	C4591001 1161 11611010	1	31JUL2020	Product administration error	DOSE NOT CHANGED	N	N	31JUL2020	N	N
	C4591001 1161 11611015	1	01AUG2020	Wrong product administered	DOSE NOT CHANGED	N	N	01AUG2020	N	N

16.2.5.2.1 Listing of Medication Errors – Subjects 12 Through 25 Years of Age										
Age Group (Years)	Subject	Dose No. ^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1212 12121013	3	25JAN2021	Product preparation error	DOSE NOT CHANGED	N	N	25JAN2021	N	N
	C4591001 1230 12301157	2	28OCT2020	Product administration error	DOSE NOT CHANGED	N	N	28OCT2020	N	N
	C4591001 1231 12313467	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313498	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313505	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313515	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313519	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313533	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313542	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N

16.2.5.2.1 Listing of Medication Errors – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	Dose No.^a	Start Date	Type of Medication Error	Action Taken	Was a Concomitant Medication Given (Yes/No)	Was the Nondrug Treatment Given (Yes/No)	Stop Date	Discontinued From Study (Yes/No)	Medication Error–Associated AE (Yes/No)
	C4591001 1231 12313546	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
	C4591001 1231 12313553	1	23AUG2020	Wrong dose	DOSE NOT CHANGED	N	N	23AUG2020	N	N
<p>a. Dose No. = the vaccination visit at which the medication error occurred.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_l002_me_all_ped</p>										

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age						
Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
12-15	BNT162b2 (30 µg)	C4591001 1005 10051328	2/1 Month	11DEC2020	31	1938
		C4591001 1005 10051412	1/Prevax	14DEC2020	1	10
			2/1 Month	09FEB2021	36	1192
		C4591001 1006 10061184	1/Prevax	30NOV2020	1	10
			2/1 Month	22JAN2021	33	1838
		C4591001 1006 10061209	1/Prevax	04DEC2020	1	273
			2/1 Month	26JAN2021	35	3923
		C4591001 1006 10061220	1/Prevax	07DEC2020	1	10
		C4591001 1006 10061227	1/Prevax	07DEC2020	1	10
		C4591001 1006 10061230	2/1 Month	02FEB2021	34	720
		C4591001 1006 10061231	2/1 Month	26JAN2021	30	2203
		C4591001 1006 10061234	2/1 Month	27JAN2021	29	926
		C4591001 1006 10061249	1/Prevax	11DEC2020	1	10
			2/1 Month	04FEB2021	36	2017
		C4591001 1006 10061256	1/Prevax	11DEC2020	1	10
			2/1 Month	01FEB2021	34	648
		C4591001 1006 10061261	1/Prevax	14DEC2020	1	10
		C4591001 1006 10061263	2/1 Month	05FEB2021	33	2026
		C4591001 1006 10061265	1/Prevax	18DEC2020	1	10
			2/1 Month	04FEB2021	30	1578
		C4591001 1006 10061274	1/Prevax	16DEC2020	1	10
			2/1 Month	05FEB2021	29	3332
		C4591001 1006 10061280	1/Prevax	17DEC2020	1	10
		C4591001 1006 10061282	1/Prevax	18DEC2020	1	10
		C4591001 1007 10071417	1/Prevax	22OCT2020	1	10

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
			2/1 Month	10DEC2020	29	1629
		C4591001 1007 10071467	1/Prevax	30NOV2020	1	10
		C4591001 1007 10071469	1/Prevax	30NOV2020	1	10
			2/1 Month	20JAN2021	31	7683
		C4591001 1007 10071471	1/Prevax	30NOV2020	1	10
		C4591001 1007 10071488	1/Prevax	01DEC2020	1	10
			2/1 Month	20JAN2021	30	889
		C4591001 1007 10071494	2/1 Month	20JAN2021	31	620
		C4591001 1007 10071504	1/Prevax	07DEC2020	1	10
			2/1 Month	27JAN2021	29	2079
		C4591001 1007 10071506	1/Prevax	07DEC2020	1	10
			2/1 Month	25JAN2021	29	1099
		C4591001 1007 10071512	1/Prevax	07DEC2020	1	10
			2/1 Month	25JAN2021	29	1171
		C4591001 1007 10071517	1/Prevax	08DEC2020	1	10
			2/1 Month	26JAN2021	29	789
		C4591001 1007 10071521	1/Prevax	08DEC2020	1	10
			2/1 Month	28JAN2021	31	1130
		C4591001 1007 10071523	1/Prevax	08DEC2020	1	10
		C4591001 1007 10071525	1/Prevax	08DEC2020	1	10
			2/1 Month	03FEB2021	37	1484
		C4591001 1007 10071526	2/1 Month	26JAN2021	29	1876
		C4591001 1007 10071529	1/Prevax	09DEC2020	1	10
			2/1 Month	27JAN2021	29	1542
		C4591001 1007 10071536	1/Prevax	09DEC2020	1	10
			2/1 Month	26JAN2021	29	921

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day^a	NT50 (Titer)
		C4591001 1007 10071537	1/Prevax	09DEC2020	1	10
			2/1 Month	27JAN2021	29	1326
		C4591001 1007 10071546	1/Prevax	10DEC2020	1	10
			2/1 Month	27JAN2021	29	1604
		C4591001 1007 10071550	1/Prevax	10DEC2020	1	10
			2/1 Month	28JAN2021	30	2537
		C4591001 1007 10071555	1/Prevax	10DEC2020	1	10
			2/1 Month	26JAN2021	29	832
		C4591001 1007 10071558	1/Prevax	14DEC2020	1	10
			2/1 Month	03FEB2021	31	3867
		C4591001 1007 10071561	1/Prevax	14DEC2020	1	10
			2/1 Month	02FEB2021	30	1933
		C4591001 1007 10071564	1/Prevax	14DEC2020	1	55
			2/1 Month	08FEB2021	34	1282
		C4591001 1007 10071567	1/Prevax	15DEC2020	1	10
			2/1 Month	02FEB2021	29	782
		C4591001 1007 10071574	1/Prevax	16DEC2020	1	10
		C4591001 1007 10071575	1/Prevax	16DEC2020	1	10
			2/1 Month	03FEB2021	29	1136
		C4591001 1007 10071579	1/Prevax	16DEC2020	1	10
			2/1 Month	08FEB2021	34	1369
		C4591001 1007 10071580	1/Prevax	16DEC2020	1	10
			2/1 Month	04FEB2021	30	1929
		C4591001 1007 10071587	1/Prevax	17DEC2020	1	10
			2/1 Month	04FEB2021	29	497
		C4591001 1008 10081754	2/1 Month	22JAN2021	32	1607

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day^a	NT50 (Titer)
		C4591001 1008 10081760	1/Prevax	07DEC2020	1	10
			2/1 Month	26JAN2021	30	866
		C4591001 1008 10081764	1/Prevax	07DEC2020	1	10
		C4591001 1008 10081770	1/Prevax	09DEC2020	1	33
			2/1 Month	27JAN2021	29	2342
		C4591001 1008 10081792	1/Prevax	14DEC2020	1	10
			2/1 Month	01FEB2021	29	865
		C4591001 1008 10081795	1/Prevax	15DEC2020	1	10
			2/1 Month	04FEB2021	29	2195
		C4591001 1008 10081797	2/1 Month	03FEB2021	30	908
		C4591001 1008 10081800	1/Prevax	16DEC2020	1	10
		C4591001 1008 10081802	1/Prevax	17DEC2020	1	10
			2/1 Month	04FEB2021	29	745
		C4591001 1008 10081805	1/Prevax	17DEC2020	1	10
			2/1 Month	05FEB2021	30	2637
		C4591001 1008 10081810	1/Prevax	18DEC2020	1	10
			2/1 Month	05FEB2021	29	2211
		C4591001 1008 10081813	1/Prevax	18DEC2020	1	10
			2/1 Month	08FEB2021	32	5462
		C4591001 1008 10081814	1/Prevax	18DEC2020	1	10
			2/1 Month	05FEB2021	29	1285
		C4591001 1008 10081818	1/Prevax	18DEC2020	1	10
			2/1 Month	05FEB2021	29	1683
		C4591001 1009 10091205	1/Prevax	15OCT2020	1	10
			2/1 Month	04DEC2020	29	726
		C4591001 1009 10091221	1/Prevax	19OCT2020	1	10

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1009 10091234	1/Prevax	21OCT2020	1	10
			2/1 Month	16DEC2020	36	5924
		C4591001 1009 10091250	2/1 Month	11DEC2020	29	1157
		C4591001 1009 10091265	1/Prevax	01DEC2020	1	10
		C4591001 1009 10091270	1/Prevax	01DEC2020	1	10
			2/1 Month	20JAN2021	29	1373
		C4591001 1009 10091272	1/Prevax	02DEC2020	1	10
			2/1 Month	19JAN2021	29	1021
		C4591001 1009 10091280	1/Prevax	03DEC2020	1	10
		C4591001 1009 10091281	1/Prevax	03DEC2020	1	10
		C4591001 1009 10091284	2/1 Month	27JAN2021	36	500
		C4591001 1009 10091298	2/1 Month	25JAN2021	29	1087
		C4591001 1009 10091310	1/Prevax	09DEC2020	1	10
			2/1 Month	01FEB2021	35	1450
		C4591001 1009 10091313	1/Prevax	09DEC2020	1	10
			2/1 Month	02FEB2021	36	719
		C4591001 1009 10091315	1/Prevax	09DEC2020	1	10
			2/1 Month	29JAN2021	33	1998
		C4591001 1009 10091318	1/Prevax	10DEC2020	1	10
			2/1 Month	27JAN2021	30	1173
		C4591001 1009 10091319	1/Prevax	10DEC2020	1	10
			2/1 Month	02FEB2021	36	735
		C4591001 1009 10091321	1/Prevax	10DEC2020	1	10
			2/1 Month	29JAN2021	31	1745
		C4591001 1009 10091322	1/Prevax	10DEC2020	1	10
			2/1 Month	28JAN2021	30	1683

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1009 10091331	1/Prevax	11DEC2020	1	10
			2/1 Month	29JAN2021	31	1549
		C4591001 1009 10091332	1/Prevax	11DEC2020	1	10
			2/1 Month	29JAN2021	31	1345
		C4591001 1009 10091335	1/Prevax	11DEC2020	1	10
			2/1 Month	29JAN2021	30	911
		C4591001 1009 10091342	2/1 Month	05FEB2021	33	860
		C4591001 1009 10091348	1/Prevax	15DEC2020	1	10
			2/1 Month	05FEB2021	31	666
		C4591001 1009 10091351	1/Prevax	16DEC2020	1	10
			2/1 Month	03FEB2021	29	905
		C4591001 1009 10091354	1/Prevax	16DEC2020	1	10
		C4591001 1009 10091355	1/Prevax	16DEC2020	1	10
			2/1 Month	11FEB2021	35	2648
		C4591001 1009 10091358	1/Prevax	17DEC2020	1	10
			2/1 Month	05FEB2021	31	6771
		C4591001 1009 10091360	1/Prevax	17DEC2020	1	10
			2/1 Month	03FEB2021	29	1416
		C4591001 1009 10091362	1/Prevax	17DEC2020	1	10
			2/1 Month	08FEB2021	29	1543
		C4591001 1009 10091364	2/1 Month	16FEB2021	29	2056
		C4591001 1013 10131822	1/Prevax	30NOV2020	1	10
		C4591001 1013 10131828	1/Prevax	02DEC2020	1	10
		C4591001 1013 10131836	1/Prevax	02DEC2020	1	10
			2/1 Month	19JAN2021	29	1012
		C4591001 1013 10131843	2/1 Month	27JAN2021	37	1034

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1013 10131845	1/Prevax	03DEC2020	1	10
			2/1 Month	21JAN2021	30	1471
		C4591001 1013 10131850	1/Prevax	03DEC2020	1	10
		C4591001 1013 10131855	1/Prevax	08DEC2020	1	10
		C4591001 1016 10161325	1/Prevax	19OCT2020	1	10
			2/1 Month	08DEC2020	29	10
		C4591001 1016 10161332	1/Prevax	21OCT2020	1	10
			2/1 Month	07DEC2020	29	1328
		C4591001 1016 10161339	1/Prevax	22OCT2020	1	10
			2/1 Month	09DEC2020	30	1677
		C4591001 1016 10161350	1/Prevax	30NOV2020	1	10
			2/1 Month	18JAN2021	29	1128
		C4591001 1016 10161356	1/Prevax	02DEC2020	1	10
		C4591001 1016 10161362	1/Prevax	04DEC2020	1	103
			2/1 Month	26JAN2021	30	4809
		C4591001 1016 10161363	1/Prevax	08DEC2020	1	130
			2/1 Month	26JAN2021	30	5530
		C4591001 1016 10161364	1/Prevax	09DEC2020	1	10
			2/1 Month	04FEB2021	36	1330
		C4591001 1039 10391247	1/Prevax	01DEC2020	1	10
			2/1 Month	19JAN2021	30	1541
		C4591001 1039 10391255	1/Prevax	07DEC2020	1	10
			2/1 Month	27JAN2021	30	2905
		C4591001 1039 10391272	1/Prevax	09DEC2020	1	10
			2/1 Month	25JAN2021	29	664
		C4591001 1039 10391276	1/Prevax	16DEC2020	1	10

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
			2/1 Month	05FEB2021	32	1472
		C4591001 1039 10391281	1/Prevax	17DEC2020	1	10
			2/1 Month	02FEB2021	29	551
		C4591001 1039 10391282	1/Prevax	18DEC2020	1	10
			2/1 Month	05FEB2021	29	1197
		C4591001 1039 10391284	1/Prevax	18DEC2020	1	10
			2/1 Month	04FEB2021	29	1202
		C4591001 1039 10391286	1/Prevax	18DEC2020	1	10
			2/1 Month	05FEB2021	29	776
		C4591001 1044 10441255	1/Prevax	01DEC2020	1	10
			2/1 Month	18JAN2021	29	4251
		C4591001 1044 10441263	1/Prevax	07DEC2020	1	10
			2/1 Month	25JAN2021	29	2680
		C4591001 1044 10441268	1/Prevax	08DEC2020	1	776
			2/1 Month	25JAN2021	29	962
		C4591001 1044 10441276	1/Prevax	09DEC2020	1	10
			2/1 Month	25JAN2021	28	1606
		C4591001 1044 10441278	1/Prevax	09DEC2020	1	10
			2/1 Month	27JAN2021	30	1422
		C4591001 1044 10441285	1/Prevax	10DEC2020	1	10
			2/1 Month	29JAN2021	31	1519
		C4591001 1044 10441291	1/Prevax	17DEC2020	1	10
			2/1 Month	03FEB2021	29	682
		C4591001 1044 10441295	1/Prevax	18DEC2020	1	10
		C4591001 1057 10571378	1/Prevax	07DEC2020	1	10
		C4591001 1057 10571395	1/Prevax	09DEC2020	1	10

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
			2/1 Month	17FEB2021	35	849
		C4591001 1057 10571403	2/1 Month	02FEB2021	30	5402
		C4591001 1057 10571409	1/Prevax	17DEC2020	1	10
		C4591001 1057 10571412	1/Prevax	17DEC2020	1	210
		C4591001 1066 10661395	2/1 Month	19JAN2021	30	743
		C4591001 1066 10661402	1/Prevax	02DEC2020	1	10
			2/1 Month	20JAN2021	31	1805
		C4591001 1066 10661408	1/Prevax	08DEC2020	1	15
		C4591001 1066 10661409	2/1 Month	26JAN2021	30	2477
		C4591001 1066 10661420	1/Prevax	17DEC2020	1	10
			2/1 Month	03FEB2021	30	2029
		C4591001 1077 10771274	1/Prevax	03DEC2020	1	10
		C4591001 1077 10771279	2/1 Month	02FEB2021	30	10
		C4591001 1077 10771284	1/Prevax	15DEC2020	1	10
			2/1 Month	03FEB2021	29	10
		C4591001 1077 10771292	2/1 Month	10FEB2021	36	841
		C4591001 1084 10841546	1/Prevax	18DEC2020	1	10
			2/1 Month	05FEB2021	31	906
		C4591001 1091 10911394	1/Prevax	02DEC2020	1	10
			2/1 Month	20JAN2021	31	1322
		C4591001 1091 10911395	2/1 Month	20JAN2021	31	1142
		C4591001 1091 10911399	1/Prevax	04DEC2020	1	10
			2/1 Month	04FEB2021	29	3079
		C4591001 1091 10911413	1/Prevax	09DEC2020	1	10
		C4591001 1091 10911416	1/Prevax	10DEC2020	1	10
			2/1 Month	27JAN2021	29	3214

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1091 10911420	2/1 Month	27JAN2021	29	1278
		C4591001 1091 10911436	2/1 Month	04FEB2021	30	910
		C4591001 1091 10911440	2/1 Month	08FEB2021	32	986
		C4591001 1123 11231439	1/Prevax	08DEC2020	1	10
		C4591001 1123 11231446	1/Prevax	09DEC2020	1	10
			2/1 Month	27JAN2021	29	890
		C4591001 1123 11231447	2/1 Month	01FEB2021	35	900
		C4591001 1123 11231455	2/1 Month	02FEB2021	30	1196
		C4591001 1123 11231458	1/Prevax	16DEC2020	1	10
			2/1 Month	01FEB2021	29	1312
		C4591001 1123 11231459	1/Prevax	16DEC2020	1	10
			2/1 Month	01FEB2021	29	1319
		C4591001 1124 11241238	1/Prevax	14DEC2020	1	10
			2/1 Month	03FEB2021	29	1576
		C4591001 1124 11241239	1/Prevax	14DEC2020	1	10
			2/1 Month	03FEB2021	29	1779
		C4591001 1124 11241243	2/1 Month	09FEB2021	36	2127
		C4591001 1124 11241249	1/Prevax	16DEC2020	1	10
		C4591001 1124 11241251	1/Prevax	18DEC2020	1	10
			2/1 Month	05FEB2021	29	7898
		C4591001 1124 11241254	2/1 Month	10FEB2021	34	1423
		C4591001 1126 11261229	1/Prevax	30NOV2020	1	10
			2/1 Month	18JAN2021	29	1085
		C4591001 1126 11261241	1/Prevax	02DEC2020	1	10
			2/1 Month	20JAN2021	31	823
		C4591001 1126 11261243	2/1 Month	22JAN2021	33	1754

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1126 11261246	1/Prevax	02DEC2020	1	10
			2/1 Month	20JAN2021	29	969
		C4591001 1126 11261255	1/Prevax	03DEC2020	1	10
			2/1 Month	26JAN2021	35	2453
		C4591001 1126 11261269	1/Prevax	14DEC2020	1	10
		C4591001 1126 11261273	1/Prevax	14DEC2020	1	10
		C4591001 1126 11261277	1/Prevax	15DEC2020	1	10
		C4591001 1126 11261278	2/1 Month	02FEB2021	29	373
		C4591001 1126 11261281	1/Prevax	16DEC2020	1	10
			2/1 Month	12FEB2021	37	1681
		C4591001 1126 11261285	1/Prevax	16DEC2020	1	10
			2/1 Month	03FEB2021	29	727
		C4591001 1126 11261291	1/Prevax	17DEC2020	1	10
			2/1 Month	04FEB2021	29	569
		C4591001 1126 11261293	1/Prevax	18DEC2020	1	10
			2/1 Month	05FEB2021	29	1419
		C4591001 1131 11311275	1/Prevax	04DEC2020	1	10
		C4591001 1131 11311278	1/Prevax	08DEC2020	1	10
			2/1 Month	27JAN2021	29	1209
		C4591001 1139 11391144	1/Prevax	11DEC2020	1	10
			2/1 Month	27JAN2021	29	1152
		C4591001 1139 11391145	1/Prevax	01DEC2020	1	10
			2/1 Month	19JAN2021	30	718
		C4591001 1139 11391151	1/Prevax	04DEC2020	1	14
		C4591001 1139 11391155	1/Prevax	04DEC2020	1	10
			2/1 Month	29JAN2021	33	2762

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day^a	NT50 (Titer)
		C4591001 1139 11391156	1/Prevax	07DEC2020	1	10
		C4591001 1139 11391161	1/Prevax	08DEC2020	1	10
			2/1 Month	01FEB2021	35	1041
		C4591001 1139 11391162	1/Prevax	08DEC2020	1	10
			2/1 Month	01FEB2021	35	788
		C4591001 1139 11391165	2/1 Month	03FEB2021	36	542
		C4591001 1139 11391178	1/Prevax	18DEC2020	1	10
			2/1 Month	05FEB2021	29	464
		C4591001 1139 11391179	1/Prevax	18DEC2020	1	10
			2/1 Month	05FEB2021	29	573
		C4591001 1140 11401328	1/Prevax	14DEC2020	1	10
			2/1 Month	05FEB2021	32	884
		C4591001 1140 11401332	1/Prevax	16DEC2020	1	10
			2/1 Month	03FEB2021	29	2191
		C4591001 1140 11401336	1/Prevax	17DEC2020	1	10
		C4591001 1140 11401337	1/Prevax	17DEC2020	1	10
		C4591001 1142 11421319	1/Prevax	01DEC2020	1	10
		C4591001 1142 11421330	1/Prevax	04DEC2020	1	10
		C4591001 1142 11421343	1/Prevax	08DEC2020	1	10
		C4591001 1142 11421346	2/1 Month	27JAN2021	30	1553
		C4591001 1142 11421350	2/1 Month	02FEB2021	35	2271
		C4591001 1142 11421353	2/1 Month	29JAN2021	30	1365
		C4591001 1142 11421360	2/1 Month	01FEB2021	29	1463
		C4591001 1142 11421362	2/1 Month	02FEB2021	30	1149
		C4591001 1147 11471262	1/Prevax	12DEC2020	1	10
			2/1 Month	06FEB2021	34	786

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1147 11471268	1/Prevax	05DEC2020	1	10
			2/1 Month	30JAN2021	34	5724
		C4591001 1147 11471277	1/Prevax	08DEC2020	1	10
			2/1 Month	30JAN2021	34	3085
		C4591001 1147 11471279	2/1 Month	30JAN2021	34	1586
		C4591001 1147 11471282	1/Prevax	12DEC2020	1	10
			2/1 Month	08FEB2021	36	2460
		C4591001 1150 11501118	1/Prevax	15OCT2020	1	10
			2/1 Month	02DEC2020	30	7031
		C4591001 1150 11501119	1/Prevax	15OCT2020	1	10
		C4591001 1150 11501127	1/Prevax	19OCT2020	1	10
			2/1 Month	09DEC2020	29	773
		C4591001 1150 11501130	1/Prevax	20OCT2020	1	110
			2/1 Month	11DEC2020	33	5987
		C4591001 1150 11501132	1/Prevax	20OCT2020	1	10
			2/1 Month	11DEC2020	33	2148
		C4591001 1150 11501133	1/Prevax	21OCT2020	1	10
			2/1 Month	08DEC2020	29	3119
		C4591001 1150 11501180	1/Prevax	08DEC2020	1	10
			2/1 Month	27JAN2021	29	849
		C4591001 1150 11501186	1/Prevax	09DEC2020	1	10
			2/1 Month	26JAN2021	29	985
		C4591001 1150 11501187	1/Prevax	09DEC2020	1	10
			2/1 Month	26JAN2021	30	1582
		C4591001 1150 11501191	1/Prevax	10DEC2020	1	10
			2/1 Month	27JAN2021	29	2704

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1150 11501194	1/Prevax	10DEC2020	1	10
			2/1 Month	02FEB2021	34	534
		C4591001 1150 11501197	1/Prevax	11DEC2020	1	10
			2/1 Month	28JAN2021	30	1129
		C4591001 1150 11501208	1/Prevax	14DEC2020	1	10
			2/1 Month	01FEB2021	29	2309
		C4591001 1150 11501211	1/Prevax	15DEC2020	1	10
			2/1 Month	04FEB2021	29	445
		C4591001 1150 11501216	1/Prevax	16DEC2020	1	10
			2/1 Month	03FEB2021	29	1142
		C4591001 1150 11501217	1/Prevax	16DEC2020	1	10
			2/1 Month	03FEB2021	30	4893
		C4591001 1150 11501221	1/Prevax	17DEC2020	1	10
			2/1 Month	12FEB2021	36	262
		C4591001 1150 11501226	1/Prevax	17DEC2020	1	10
			2/1 Month	08FEB2021	32	1910
		C4591001 1150 11501227	2/1 Month	08FEB2021	34	974
		C4591001 1152 11521605	1/Prevax	02DEC2020	1	10
			2/1 Month	19JAN2021	29	2146
		C4591001 1152 11521614	1/Prevax	03DEC2020	1	10
			2/1 Month	19JAN2021	29	1241
		C4591001 1152 11521619	1/Prevax	03DEC2020	1	10
			2/1 Month	25JAN2021	35	1721
		C4591001 1152 11521625	1/Prevax	04DEC2020	1	10
		C4591001 1152 11521635	2/1 Month	25JAN2021	29	1164
		C4591001 1152 11521636	2/1 Month	25JAN2021	29	1086

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1152 11521648	2/1 Month	28JAN2021	32	1471
		C4591001 1152 11521650	1/Prevax	08DEC2020	1	10
			2/1 Month	25JAN2021	29	836
		C4591001 1152 11521655	1/Prevax	09DEC2020	1	10
			2/1 Month	26JAN2021	29	550
		C4591001 1152 11521656	1/Prevax	10DEC2020	1	10
		C4591001 1152 11521657	1/Prevax	10DEC2020	1	10
		C4591001 1152 11521671	2/1 Month	01FEB2021	29	2569
		C4591001 1152 11521674	2/1 Month	08FEB2021	32	866
		C4591001 1152 11521677	1/Prevax	15DEC2020	1	10
			2/1 Month	01FEB2021	29	3484
		C4591001 1152 11521679	1/Prevax	15DEC2020	1	19
		C4591001 1152 11521689	1/Prevax	16DEC2020	1	10
		C4591001 1152 11521692	1/Prevax	16DEC2020	1	10
			2/1 Month	08FEB2021	34	1820
		C4591001 1152 11521694	1/Prevax	16DEC2020	1	10
			2/1 Month	03FEB2021	29	1327
		C4591001 1152 11521697	1/Prevax	18DEC2020	1	10
		C4591001 1152 11521699	2/1 Month	10FEB2021	34	1710
		C4591001 1156 11561243	1/Prevax	15OCT2020	1	10
			2/1 Month	02DEC2020	30	315
		C4591001 1156 11561245	1/Prevax	15OCT2020	1	10
			2/1 Month	02DEC2020	30	862
		C4591001 1156 11561249	1/Prevax	16OCT2020	1	10
			2/1 Month	03DEC2020	30	887
		C4591001 1156 11561250	1/Prevax	16OCT2020	1	10

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
			2/1 Month	02DEC2020	29	115
		C4591001 1156 11561257	1/Prevax	20OCT2020	1	10
		C4591001 1156 11561259	1/Prevax	20OCT2020	1	10
			2/1 Month	09DEC2020	30	894
		C4591001 1156 11561264	2/1 Month	14DEC2020	35	1483
		C4591001 1156 11561304	1/Prevax	30NOV2020	1	10
		C4591001 1156 11561310	1/Prevax	01DEC2020	1	10
			2/1 Month	05FEB2021	30	1842
		C4591001 1156 11561313	2/1 Month	20JAN2021	31	1231
		C4591001 1156 11561314	2/1 Month	22JAN2021	31	3575
		C4591001 1156 11561317	2/1 Month	26JAN2021	30	1194
		C4591001 1156 11561321	1/Prevax	07DEC2020	1	10
		C4591001 1156 11561324	1/Prevax	07DEC2020	1	10
		C4591001 1235 12351233	2/1 Month	19JAN2021	30	877
		C4591001 1235 12351242	2/1 Month	28JAN2021	32	1058
		C4591001 1235 12351245	1/Prevax	08DEC2020	1	10
			2/1 Month	29JAN2021	31	1364
		C4591001 1235 12351246	1/Prevax	15DEC2020	1	10
		C4591001 1235 12351250	2/1 Month	02FEB2021	29	1385
		C4591001 1270 12701184	1/Prevax	02DEC2020	1	10
			2/1 Month	20JAN2021	29	1735
		C4591001 1270 12701187	1/Prevax	03DEC2020	1	10
		C4591001 1270 12701200	1/Prevax	10DEC2020	1	10
			2/1 Month	27JAN2021	30	2018
		C4591001 1270 12701210	1/Prevax	16DEC2020	1	10
			2/1 Month	03FEB2021	31	647

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
	Placebo	C4591001 1270 12701214	2/1 Month	09FEB2021	33	1900
		C4591001 1270 12701220	2/1 Month	08FEB2021	32	1111
		C4591001 1005 10051419	2/1 Month	01FEB2021	29	10
		C4591001 1006 10061212	1/Prevax	04DEC2020	1	10
		C4591001 1006 10061248	1/Prevax	11DEC2020	1	10
		C4591001 1007 10071481	1/Prevax	01DEC2020	1	10
			2/1 Month	20JAN2021	30	10
		C4591001 1007 10071541	1/Prevax	09DEC2020	1	10
			2/1 Month	28JAN2021	30	10
		C4591001 1007 10071560	1/Prevax	14DEC2020	1	10
			2/1 Month	02FEB2021	29	10
		C4591001 1007 10071562	1/Prevax	14DEC2020	1	251
			2/1 Month	01FEB2021	29	285
		C4591001 1008 10081808	1/Prevax	18DEC2020	1	10
			2/1 Month	12FEB2021	36	10
		C4591001 1009 10091233	1/Prevax	21OCT2020	1	10
			2/1 Month	14DEC2020	33	10
		C4591001 1009 10091273	1/Prevax	02DEC2020	1	10
			2/1 Month	19JAN2021	29	10
		C4591001 1009 10091314	1/Prevax	09DEC2020	1	10
			2/1 Month	01FEB2021	34	68
		C4591001 1009 10091317	2/1 Month	27JAN2021	30	10
		C4591001 1009 10091341	2/1 Month	05FEB2021	33	10
		C4591001 1013 10131848	1/Prevax	03DEC2020	1	10
			2/1 Month	20JAN2021	30	10
		C4591001 1013 10131867	1/Prevax	17DEC2020	1	10

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
			2/1 Month	03FEB2021	30	10
		C4591001 1016 10161324	1/Prevax	19OCT2020	1	10
			2/1 Month	07DEC2020	29	10
		C4591001 1016 10161340	1/Prevax	22OCT2020	1	10
			2/1 Month	09DEC2020	30	10
		C4591001 1016 10161361	1/Prevax	04DEC2020	1	10
			2/1 Month	22JAN2021	31	67
		C4591001 1039 10391256	1/Prevax	07DEC2020	1	10
			2/1 Month	27JAN2021	30	10
		C4591001 1044 10441260	1/Prevax	01DEC2020	1	10
			2/1 Month	20JAN2021	30	10
		C4591001 1057 10571400	1/Prevax	11DEC2020	1	37
		C4591001 1066 10661394	2/1 Month	27JAN2021	29	128
		C4591001 1066 10661405	2/1 Month	21JAN2021	31	10
		C4591001 1091 10911400	1/Prevax	04DEC2020	1	10
			2/1 Month	27JAN2021	30	10
		C4591001 1091 10911407	1/Prevax	08DEC2020	1	10
			2/1 Month	25JAN2021	29	621
		C4591001 1091 10911424	1/Prevax	15DEC2020	1	18
			2/1 Month	01FEB2021	29	27
		C4591001 1123 11231431	1/Prevax	04DEC2020	1	10
		C4591001 1123 11231438	1/Prevax	08DEC2020	1	10
		C4591001 1123 11231441	1/Prevax	09DEC2020	1	10
		C4591001 1123 11231448	1/Prevax	11DEC2020	1	10
		C4591001 1124 11241248	2/1 Month	03FEB2021	29	10
		C4591001 1126 11261267	1/Prevax	14DEC2020	1	10

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
			2/1 Month	03FEB2021	31	10
		C4591001 1140 11401327	1/Prevax	11DEC2020	1	10
			2/1 Month	02FEB2021	29	10
		C4591001 1140 11401335	1/Prevax	17DEC2020	1	10
			2/1 Month	10FEB2021	36	10
		C4591001 1142 11421335	1/Prevax	04DEC2020	1	10
			2/1 Month	22JAN2021	31	10
		C4591001 1150 11501179	1/Prevax	07DEC2020	1	10
			2/1 Month	29JAN2021	33	10
		C4591001 1150 11501210	1/Prevax	15DEC2020	1	10
			2/1 Month	04FEB2021	29	10
		C4591001 1152 11521637	1/Prevax	07DEC2020	1	10
			2/1 Month	25JAN2021	29	10
		C4591001 1152 11521661	1/Prevax	10DEC2020	1	10
		C4591001 1152 11521667	1/Prevax	11DEC2020	1	10
		C4591001 1152 11521686	1/Prevax	16DEC2020	1	10
		C4591001 1152 11521701	2/1 Month	03FEB2021	29	10
		C4591001 1156 11561246	1/Prevax	22OCT2020	1	10
			2/1 Month	08DEC2020	29	10
		C4591001 1156 11561311	1/Prevax	02DEC2020	1	10
		C4591001 1270 12701173	1/Prevax	30NOV2020	1	10
			2/1 Month	18JAN2021	29	10
		C4591001 1270 12701174	1/Prevax	30NOV2020	1	10
			2/1 Month	18JAN2021	29	10
		C4591001 1270 12701218	1/Prevax	17DEC2020	1	10
			2/1 Month	05FEB2021	30	10

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
16-25	BNT162b2 (30 µg)	C4591001 1001 10011085	1/Prevax	28JUL2020	1	10
			2/1 Month	21SEP2020	34	172
		C4591001 1005 10051400	1/Prevax	03NOV2020	1	10
			2/1 Month	21DEC2020	29	707
		C4591001 1005 10051416	1/Prevax	16DEC2020	1	10
			2/1 Month	10FEB2021	36	502
		C4591001 1006 10061137	1/Prevax	01SEP2020	1	10
		C4591001 1006 10061162	1/Prevax	25SEP2020	1	10
			2/1 Month	18NOV2020	34	1223
		C4591001 1006 10061170	1/Prevax	05OCT2020	1	10
			2/1 Month	25NOV2020	29	1617
		C4591001 1006 10061192	2/1 Month	26JAN2021	36	891
		C4591001 1006 10061202	1/Prevax	03DEC2020	1	10
			2/1 Month	19JAN2021	29	1184
		C4591001 1006 10061225	1/Prevax	07DEC2020	1	10
			2/1 Month	29JAN2021	33	854
		C4591001 1007 10071289	1/Prevax	27AUG2020	1	10
			2/1 Month	15OCT2020	29	737
		C4591001 1007 10071385	1/Prevax	20OCT2020	1	10
			2/1 Month	08DEC2020	29	1033
		C4591001 1007 10071434	1/Prevax	27OCT2020	1	10
		C4591001 1007 10071439	2/1 Month	21DEC2020	33	668
		C4591001 1007 10071447	1/Prevax	11NOV2020	1	10
		C4591001 1007 10071454	1/Prevax	12NOV2020	1	10
		C4591001 1007 10071473	1/Prevax	07DEC2020	1	10
		C4591001 1008 10081558	2/1 Month	25NOV2020	34	466

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1008 10081747	2/1 Month	08JAN2021	29	968
		C4591001 1009 10091028	1/Prevax	12AUG2020	1	10
			2/1 Month	05OCT2020	36	775
		C4591001 1009 10091070	1/Prevax	19AUG2020	1	10
			2/1 Month	12OCT2020	34	267
		C4591001 1009 10091217	1/Prevax	16OCT2020	1	10
			2/1 Month	04DEC2020	29	668
		C4591001 1009 10091256	2/1 Month	22DEC2020	34	2293
		C4591001 1011 10111215	1/Prevax	19OCT2020	1	10
			2/1 Month	09DEC2020	29	6340
		C4591001 1013 10131002	1/Prevax	28JUL2020	1	10
			2/1 Month	14SEP2020	29	1040
		C4591001 1013 10131026	1/Prevax	30JUL2020	1	10
			2/1 Month	30SEP2020	42	654
		C4591001 1013 10131059	1/Prevax	03AUG2020	1	10
			2/1 Month	21SEP2020	28	697
		C4591001 1013 10131171	1/Prevax	13AUG2020	1	10
			2/1 Month	01OCT2020	29	1364
		C4591001 1013 10131276	1/Prevax	24AUG2020	1	10
		C4591001 1013 10131653	1/Prevax	07OCT2020	1	10
		C4591001 1013 10131829	1/Prevax	02DEC2020	1	10
		C4591001 1015 10151081	1/Prevax	21AUG2020	1	10
			2/1 Month	09OCT2020	29	256
		C4591001 1015 10151150	1/Prevax	31AUG2020	1	10
		C4591001 1016 10161010	1/Prevax	30JUL2020	1	10
			2/1 Month	22SEP2020	35	461

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age						
Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1016 10161028	1/Prevax	03AUG2020	1	10
			2/1 Month	06OCT2020	29	982
		C4591001 1016 10161284	1/Prevax	11SEP2020	1	10
			2/1 Month	29OCT2020	30	483
		C4591001 1016 10161288	1/Prevax	17SEP2020	1	17
			2/1 Month	05NOV2020	31	1041
		C4591001 1016 10161289	1/Prevax	18SEP2020	1	10
			2/1 Month	06NOV2020	31	468
		C4591001 1016 10161293	1/Prevax	21SEP2020	1	10
			2/1 Month	09NOV2020	29	1484
		C4591001 1016 10161295	1/Prevax	22SEP2020	1	10
			2/1 Month	10NOV2020	29	1716
		C4591001 1018 10181007	1/Prevax	29JUL2020	1	10
			2/1 Month	23SEP2020	36	511
		C4591001 1018 10181194	1/Prevax	20AUG2020	1	10
			2/1 Month	19OCT2020	33	844
		C4591001 1022 10221112	1/Prevax	02SEP2020	1	10
			2/1 Month	22OCT2020	29	1593
		C4591001 1028 10281029	1/Prevax	20AUG2020	1	10
			2/1 Month	08OCT2020	29	1084
		C4591001 1028 10281053	1/Prevax	25AUG2020	1	10
			2/1 Month	14OCT2020	29	1673
		C4591001 1030 10301072	1/Prevax	11SEP2020	1	10
			2/1 Month	30OCT2020	29	460
		C4591001 1038 10381006	1/Prevax	19AUG2020	1	10
			2/1 Month	07OCT2020	29	552

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age						
Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1042 10421004	1/Prevax	29JUL2020	1	10
			2/1 Month	25SEP2020	36	187
		C4591001 1042 10421114	1/Prevax	17AUG2020	1	10
			2/1 Month	07OCT2020	29	295
		C4591001 1044 10441193	1/Prevax	17OCT2020	1	10
			2/1 Month	03DEC2020	29	1191
		C4591001 1044 10441235	1/Prevax	25NOV2020	1	10
			2/1 Month	18JAN2021	33	1599
		C4591001 1044 10441241	1/Prevax	23NOV2020	1	10
			2/1 Month	13JAN2021	30	1465
		C4591001 1044 10441272	1/Prevax	08DEC2020	1	10
			2/1 Month	29JAN2021	33	746
		C4591001 1046 10461125	1/Prevax	27AUG2020	1	10
			2/1 Month	20OCT2020	34	977
		C4591001 1046 10461171	1/Prevax	02SEP2020	1	10
			2/1 Month	26OCT2020	34	222
		C4591001 1046 10461319	1/Prevax	26OCT2020	1	10
			2/1 Month	14DEC2020	29	612
		C4591001 1046 10461338	1/Prevax	30OCT2020	1	10
			2/1 Month	18DEC2020	29	1517
		C4591001 1046 10461346	1/Prevax	01DEC2020	1	10
		C4591001 1047 10471275	1/Prevax	23SEP2020	1	10
		C4591001 1047 10471306	1/Prevax	02OCT2020	1	10
		C4591001 1054 10541007	1/Prevax	19AUG2020	1	10
			2/1 Month	06OCT2020	29	658
		C4591001 1054 10541090	1/Prevax	01SEP2020	1	10

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
			2/1 Month	20OCT2020	29	905
		C4591001 1055 10551021	1/Prevax	11AUG2020	1	10
			2/1 Month	29SEP2020	30	858
		C4591001 1057 10571044	2/1 Month	07OCT2020	29	164
		C4591001 1057 10571217	1/Prevax	21SEP2020	1	10
			2/1 Month	07DEC2020	56	273
		C4591001 1057 10571234	1/Prevax	23SEP2020	1	10
			2/1 Month	11NOV2020	29	264
		C4591001 1057 10571366	1/Prevax	23NOV2020	1	10
		C4591001 1057 10571368	1/Prevax	23NOV2020	1	83
		C4591001 1066 10661166	1/Prevax	02SEP2020	1	10
			2/1 Month	21OCT2020	29	615
		C4591001 1068 10681098	1/Prevax	03SEP2020	1	10
			2/1 Month	22OCT2020	29	318
		C4591001 1068 10681119	1/Prevax	10SEP2020	1	10
		C4591001 1071 10711233	1/Prevax	19OCT2020	1	10
			2/1 Month	10DEC2020	30	164
		C4591001 1077 10771262	1/Prevax	20OCT2020	1	10
			2/1 Month	07DEC2020	29	258
		C4591001 1077 10771273	1/Prevax	02DEC2020	1	10
			2/1 Month	25JAN2021	35	505
		C4591001 1079 10791288	1/Prevax	16SEP2020	1	10
			2/1 Month	04NOV2020	29	1001
		C4591001 1082 10821014	1/Prevax	03AUG2020	1	10
			2/1 Month	22SEP2020	29	240
		C4591001 1082 10821036	2/1 Month	21SEP2020	28	1333

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1082 10821196	2/1 Month	30NOV2020	34	903
		C4591001 1082 10821201	1/Prevax	19OCT2020	1	10
			2/1 Month	08DEC2020	30	738
		C4591001 1084 10841423	1/Prevax	18SEP2020	1	66
		C4591001 1085 10851050	1/Prevax	06AUG2020	1	10
			2/1 Month	30SEP2020	29	675
		C4591001 1087 10871214	1/Prevax	26AUG2020	1	10
			2/1 Month	15OCT2020	29	241
		C4591001 1087 10871267	1/Prevax	31AUG2020	1	10
			2/1 Month	19OCT2020	29	217
		C4591001 1087 10871529	1/Prevax	29SEP2020	1	10
			2/1 Month	17NOV2020	29	128
		C4591001 1087 10871565	1/Prevax	15OCT2020	1	10
		C4591001 1088 10881200	1/Prevax	11SEP2020	1	10
		C4591001 1089 10891273	1/Prevax	09SEP2020	1	10
			2/1 Month	30OCT2020	29	1424
		C4591001 1089 10891306	2/1 Month	03NOV2020	30	605
		C4591001 1090 10901031	1/Prevax	03AUG2020	1	10
			2/1 Month	23SEP2020	31	780
		C4591001 1090 10901043	1/Prevax	04AUG2020	1	10
			2/1 Month	23SEP2020	31	2024
		C4591001 1090 10901157	1/Prevax	12AUG2020	1	10
			2/1 Month	02OCT2020	33	594
		C4591001 1090 10901328	1/Prevax	03SEP2020	1	10
		C4591001 1090 10901443	1/Prevax	22SEP2020	1	10
			2/1 Month	13NOV2020	30	271

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1090 10901517	1/Prevax	20OCT2020	1	10
			2/1 Month	09DEC2020	29	1154
		C4591001 1090 10901559	2/1 Month	22DEC2020	36	529
		C4591001 1091 10911382	1/Prevax	28OCT2020	1	10
			2/1 Month	16DEC2020	29	2243
		C4591001 1091 10911389	1/Prevax	18NOV2020	1	10
		C4591001 1091 10911391	1/Prevax	25NOV2020	1	10
		C4591001 1091 10911401	1/Prevax	04DEC2020	1	10
			2/1 Month	27JAN2021	30	1504
		C4591001 1092 10921146	1/Prevax	02SEP2020	1	10
			2/1 Month	14JAN2021	113	214
		C4591001 1093 10931088	1/Prevax	31AUG2020	1	18
			2/1 Month	19OCT2020	29	1181
		C4591001 1093 10931174	1/Prevax	12OCT2020	1	100
		C4591001 1094 10941069	1/Prevax	28AUG2020	1	10
			2/1 Month	19OCT2020	33	649
		C4591001 1095 10951170	1/Prevax	29AUG2020	1	10
			2/1 Month	16OCT2020	30	10629
		C4591001 1095 10951271	1/Prevax	08OCT2020	1	10
		C4591001 1095 10951315	2/1 Month	12JAN2021	29	1285
		C4591001 1096 10961010	1/Prevax	13AUG2020	1	10
			2/1 Month	29SEP2020	29	169
		C4591001 1096 10961032	1/Prevax	14AUG2020	1	10
		C4591001 1096 10961168	1/Prevax	28AUG2020	1	10
			2/1 Month	21OCT2020	35	633
		C4591001 1096 10961196	1/Prevax	31AUG2020	1	162

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1096 10961219	2/1 Month	20OCT2020	30	441
		C4591001 1096 10961319	1/Prevax	12SEP2020	1	10
			2/1 Month	02NOV2020	33	424
		C4591001 1096 10961392	1/Prevax	23NOV2020	1	10
		C4591001 1098 10981177	1/Prevax	16SEP2020	1	10
		C4591001 1101 11011033	1/Prevax	10SEP2020	1	71
			2/1 Month	29OCT2020	29	1018
		C4591001 1101 11011062	2/1 Month	04NOV2020	29	1345
		C4591001 1101 11011079	1/Prevax	18SEP2020	1	10
			2/1 Month	06NOV2020	29	1885
		C4591001 1101 11011088	1/Prevax	22SEP2020	1	39
			2/1 Month	12NOV2020	31	1851
		C4591001 1109 11091020	1/Prevax	30JUL2020	1	10
			2/1 Month	15SEP2020	29	386
		C4591001 1109 11091370	1/Prevax	29AUG2020	1	10
			2/1 Month	15OCT2020	29	796
		C4591001 1109 11091391	1/Prevax	01SEP2020	1	10
		C4591001 1111 11111001	1/Prevax	30JUL2020	1	10
			2/1 Month	17SEP2020	29	2220
		C4591001 1111 11111183	1/Prevax	21SEP2020	1	10
		C4591001 1112 11121019	2/1 Month	24SEP2020	34	323
		C4591001 1112 11121217	1/Prevax	03SEP2020	1	10
			2/1 Month	26OCT2020	34	280
		C4591001 1112 11121297	1/Prevax	12OCT2020	1	10
			2/1 Month	30NOV2020	29	399
		C4591001 1114 11141021	1/Prevax	13AUG2020	1	10

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1116 11161256	1/Prevax	19SEP2020	1	10
			2/1 Month	12NOV2020	32	879
		C4591001 1116 11161320	1/Prevax	25SEP2020	1	10
		C4591001 1117 11171113	2/1 Month	04NOV2020	30	671
		C4591001 1118 11181017	2/1 Month	05OCT2020	33	745
		C4591001 1118 11181101	2/1 Month	15OCT2020	29	879
		C4591001 1120 11201337	1/Prevax	16OCT2020	1	10
			2/1 Month	04JAN2021	60	1180
		C4591001 1123 11231116	1/Prevax	17AUG2020	1	10
			2/1 Month	07OCT2020	30	1295
		C4591001 1123 11231381	1/Prevax	15OCT2020	1	10
			2/1 Month	09DEC2020	34	2476
		C4591001 1123 11231383	1/Prevax	15OCT2020	1	10
			2/1 Month	07DEC2020	33	596
		C4591001 1123 11231413	2/1 Month	13JAN2021	36	1210
		C4591001 1123 11231417	1/Prevax	23NOV2020	1	10
		C4591001 1123 11231423	2/1 Month	18JAN2021	29	475
		C4591001 1123 11231429	1/Prevax	03DEC2020	1	10
		C4591001 1124 11241071	1/Prevax	19AUG2020	1	10
			2/1 Month	14OCT2020	35	770
		C4591001 1125 11251144	1/Prevax	02SEP2020	1	10
			2/1 Month	27OCT2020	29	5632
		C4591001 1125 11251240	1/Prevax	20NOV2020	1	10
		C4591001 1126 11261216	2/1 Month	13JAN2021	30	607
		C4591001 1126 11261231	1/Prevax	30NOV2020	1	10
		C4591001 1126 11261242	1/Prevax	02DEC2020	1	14

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
			2/1 Month	22JAN2021	33	2069
		C4591001 1127 11271021	2/1 Month	15SEP2020	29	725
		C4591001 1127 11271033	2/1 Month	18SEP2020	31	251
		C4591001 1129 11291262	1/Prevax	23NOV2020	1	10
			2/1 Month	11JAN2021	29	693
		C4591001 1130 11301089	1/Prevax	21OCT2020	1	10
			2/1 Month	09DEC2020	29	130
		C4591001 1131 11311064	1/Prevax	21AUG2020	1	10
		C4591001 1131 11311266	1/Prevax	18NOV2020	1	17
			2/1 Month	11JAN2021	35	1186
		C4591001 1131 11311268	1/Prevax	23NOV2020	1	10
		C4591001 1133 11331485	1/Prevax	21SEP2020	1	10
		C4591001 1133 11331602	2/1 Month	17DEC2020	29	10
		C4591001 1134 11341327	2/1 Month	06NOV2020	36	280
		C4591001 1135 11351088	1/Prevax	08AUG2020	1	10
			2/1 Month	25SEP2020	29	1168
		C4591001 1135 11351113	1/Prevax	13AUG2020	1	10
			2/1 Month	09OCT2020	32	1428
		C4591001 1135 11351216	1/Prevax	26AUG2020	1	10
			2/1 Month	16OCT2020	29	1244
		C4591001 1135 11351355	1/Prevax	15SEP2020	1	311
			2/1 Month	04NOV2020	30	805
		C4591001 1135 11351410	2/1 Month	09NOV2020	29	1697
		C4591001 1136 11361007	1/Prevax	18AUG2020	1	10
			2/1 Month	12OCT2020	32	776
		C4591001 1139 11391141	1/Prevax	24NOV2020	1	10

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
			2/1 Month	14JAN2021	31	2154
		C4591001 1140 11401006	1/Prevax	30JUL2020	1	10
			2/1 Month	16SEP2020	29	627
		C4591001 1141 11411006	1/Prevax	31JUL2020	1	35
		C4591001 1141 11411072	1/Prevax	13AUG2020	1	10
			2/1 Month	02OCT2020	31	362
		C4591001 1141 11411081	1/Prevax	14AUG2020	1	10
			2/1 Month	07OCT2020	36	395
		C4591001 1141 11411141	1/Prevax	27AUG2020	1	10
			2/1 Month	15OCT2020	29	633
		C4591001 1141 11411187	2/1 Month	29OCT2020	29	1723
		C4591001 1141 11411227	2/1 Month	10NOV2020	33	1738
		C4591001 1141 11411236	2/1 Month	13NOV2020	36	363
		C4591001 1141 11411263	1/Prevax	19OCT2020	1	10
			2/1 Month	07DEC2020	29	1138
		C4591001 1141 11411269	1/Prevax	27OCT2020	1	10
		C4591001 1142 11421037	1/Prevax	04AUG2020	1	10
			2/1 Month	29SEP2020	33	794
		C4591001 1142 11421100	1/Prevax	14AUG2020	1	10
			2/1 Month	02OCT2020	30	1055
		C4591001 1142 11421274	1/Prevax	07OCT2020	1	10
			2/1 Month	02DEC2020	36	678
		C4591001 1142 11421338	1/Prevax	04DEC2020	1	10
		C4591001 1146 11461292	2/1 Month	14DEC2020	33	487
		C4591001 1146 11461316	2/1 Month	11DEC2020	31	1103
		C4591001 1146 11461378	2/1 Month	15DEC2020	29	490

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1147 11471255	1/Prevax	14NOV2020	1	10
			2/1 Month	11JAN2021	38	1087
		C4591001 1149 11491050	1/Prevax	11AUG2020	1	10
			2/1 Month	30SEP2020	30	270
		C4591001 1149 11491079	1/Prevax	17AUG2020	1	10
		C4591001 1149 11491218	1/Prevax	08SEP2020	1	10
			2/1 Month	27OCT2020	29	793
		C4591001 1149 11491255	1/Prevax	18SEP2020	1	10
			2/1 Month	11NOV2020	34	299
		C4591001 1149 11491302	1/Prevax	24SEP2020	1	10
		C4591001 1150 11501016	1/Prevax	19AUG2020	1	10
		C4591001 1150 11501181	2/1 Month	01FEB2021	36	343
		C4591001 1152 11521011	2/1 Month	30SEP2020	30	551
		C4591001 1152 11521019	1/Prevax	12AUG2020	1	10
			2/1 Month	30SEP2020	29	1086
		C4591001 1152 11521114	1/Prevax	19AUG2020	1	10
			2/1 Month	09OCT2020	30	1078
		C4591001 1152 11521115	1/Prevax	19AUG2020	1	10
		C4591001 1152 11521149	2/1 Month	09OCT2020	29	653
		C4591001 1152 11521164	1/Prevax	24AUG2020	1	10
			2/1 Month	12OCT2020	29	481
		C4591001 1152 11521357	2/1 Month	21OCT2020	29	700
		C4591001 1152 11521451	1/Prevax	16SEP2020	1	10
		C4591001 1152 11521464	1/Prevax	18SEP2020	1	10
		C4591001 1152 11521505	1/Prevax	09OCT2020	1	10
			2/1 Month	04DEC2020	36	536

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1152 11521534	1/Prevax	16OCT2020	1	10
			2/1 Month	02DEC2020	29	313
		C4591001 1152 11521587	1/Prevax	16NOV2020	1	10
			2/1 Month	04JAN2021	29	1075
		C4591001 1152 11521588	1/Prevax	16NOV2020	1	10
			2/1 Month	04JAN2021	29	177
		C4591001 1152 11521589	1/Prevax	17NOV2020	1	10
			2/1 Month	06JAN2021	31	1948
		C4591001 1152 11521600	1/Prevax	24NOV2020	1	10
			2/1 Month	12JAN2021	29	1272
		C4591001 1152 11521601	1/Prevax	24NOV2020	1	10
			2/1 Month	19JAN2021	36	2877
		C4591001 1152 11521634	2/1 Month	25JAN2021	29	455
		C4591001 1156 11561155	2/1 Month	13NOV2020	36	1224
		C4591001 1156 11561229	1/Prevax	12OCT2020	1	10
			2/1 Month	03DEC2020	30	7789
		C4591001 1156 11561258	1/Prevax	20OCT2020	1	17
			2/1 Month	14DEC2020	34	797
		C4591001 1156 11561288	1/Prevax	30OCT2020	1	10
		C4591001 1156 11561291	1/Prevax	30OCT2020	1	10
			2/1 Month	17DEC2020	29	241
		C4591001 1162 11621051	2/1 Month	25SEP2020	29	1609
		C4591001 1162 11621110	1/Prevax	13AUG2020	1	10
			2/1 Month	06OCT2020	35	308
		C4591001 1162 11621418	2/1 Month	12NOV2020	32	795
		C4591001 1163 11631048	1/Prevax	06AUG2020	1	10

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
			2/1 Month	22SEP2020	29	1942
		C4591001 1163 11631106	2/1 Month	29SEP2020	29	268
		C4591001 1166 11661008	1/Prevax	18AUG2020	1	10
			2/1 Month	06OCT2020	29	168
		C4591001 1166 11661048	1/Prevax	31AUG2020	1	10
			2/1 Month	21OCT2020	31	970
		C4591001 1167 11671142	1/Prevax	04SEP2020	1	10
			2/1 Month	21OCT2020	29	95
		C4591001 1167 11671224	1/Prevax	24SEP2020	1	10
			2/1 Month	12NOV2020	31	337
		C4591001 1168 11681035	1/Prevax	17AUG2020	1	10
			2/1 Month	06OCT2020	29	755
		C4591001 1168 11681069	1/Prevax	21AUG2020	1	10
		C4591001 1168 11681098	2/1 Month	15OCT2020	29	919
		C4591001 1168 11681135	1/Prevax	03SEP2020	1	10
			2/1 Month	30OCT2020	29	935
		C4591001 1168 11681219	2/1 Month	02DEC2020	35	4878
		C4591001 1168 11681224	1/Prevax	08OCT2020	1	10
			2/1 Month	01DEC2020	35	555
		C4591001 1171 11711027	1/Prevax	14AUG2020	1	10
			2/1 Month	02OCT2020	29	1685
		C4591001 1171 11711211	1/Prevax	09SEP2020	1	10
		C4591001 1171 11711240	1/Prevax	11SEP2020	1	10
			2/1 Month	06NOV2020	37	939
		C4591001 1177 11771393	2/1 Month	06NOV2020	29	866
		C4591001 1177 11771428	2/1 Month	12NOV2020	29	1045

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1177 11771540	1/Prevax	20OCT2020	1	10
		C4591001 1177 11771550	2/1 Month	09DEC2020	29	920
		C4591001 1178 11781098	2/1 Month	23OCT2020	29	318
		C4591001 1178 11781156	1/Prevax	11SEP2020	1	10
			2/1 Month	29OCT2020	29	499
		C4591001 1178 11781161	1/Prevax	11SEP2020	1	10
			2/1 Month	02NOV2020	33	536
		C4591001 1178 11781187	1/Prevax	16SEP2020	1	10
			2/1 Month	09NOV2020	34	905
		C4591001 1178 11781301	1/Prevax	14OCT2020	1	10
			2/1 Month	02DEC2020	30	144
		C4591001 1204 12041088	1/Prevax	10SEP2020	1	10
			2/1 Month	13NOV2020	43	596
		C4591001 1204 12041275	1/Prevax	21OCT2020	1	10
		C4591001 1221 12211036	1/Prevax	16NOV2020	1	10
		C4591001 1223 12231117	1/Prevax	05SEP2020	1	10
			2/1 Month	27OCT2020	30	745
		C4591001 1224 12241136	1/Prevax	04SEP2020	1	10
			2/1 Month	30OCT2020	37	1027
		C4591001 1224 12241187	1/Prevax	04DEC2020	1	10
		C4591001 1232 12321028	1/Prevax	17AUG2020	1	10
			2/1 Month	06OCT2020	29	393
		C4591001 1232 12321302	1/Prevax	06OCT2020	1	10
		C4591001 1235 12351003	2/1 Month	20OCT2020	29	574
		C4591001 1235 12351014	1/Prevax	04SEP2020	1	10
		C4591001 1235 12351053	2/1 Month	27OCT2020	29	2872

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1235 12351230	1/Prevax	03NOV2020	1	10
		C4591001 1241 12411885	1/Prevax	18SEP2020	1	10
			2/1 Month	13NOV2020	36	570
		C4591001 1248 12481033	1/Prevax	29AUG2020	1	10
			2/1 Month	21OCT2020	32	360
		C4591001 1248 12481038	1/Prevax	30AUG2020	1	10
			2/1 Month	19OCT2020	30	694
		C4591001 1254 12541193	2/1 Month	05DEC2020	29	636
		C4591001 1258 12581023	1/Prevax	09SEP2020	1	10
			2/1 Month	02NOV2020	29	2021
		C4591001 1258 12581065	2/1 Month	07DEC2020	29	1777
		C4591001 1264 12641095	1/Prevax	02SEP2020	1	10
		C4591001 1270 12701153	1/Prevax	12NOV2020	1	10
			2/1 Month	06JAN2021	36	569
		C4591001 1270 12701156	1/Prevax	18NOV2020	1	10
			2/1 Month	07JAN2021	30	1528
		C4591001 1270 12701169	2/1 Month	18JAN2021	34	618
	Placebo	C4591001 1003 10031111	1/Prevax	30JUL2020	1	10
			2/1 Month	23SEP2020	35	10
		C4591001 1006 10061136	1/Prevax	01SEP2020	1	10
			2/1 Month	20OCT2020	29	10
		C4591001 1006 10061159	1/Prevax	24SEP2020	1	10
		C4591001 1006 10061194	1/Prevax	02DEC2020	1	10
			2/1 Month	20JAN2021	29	10
		C4591001 1007 10071082	1/Prevax	28JUL2020	1	10
			2/1 Month	16SEP2020	29	10

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age						
Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1009 10091235	1/Prevax	21OCT2020	1	10
		C4591001 1013 10131005	1/Prevax	28JUL2020	1	10
			2/1 Month	16SEP2020	29	10
		C4591001 1013 10131020	1/Prevax	30JUL2020	1	10
			2/1 Month	21SEP2020	34	10
		C4591001 1013 10131060	1/Prevax	03AUG2020	1	10
			2/1 Month	21SEP2020	29	10
		C4591001 1016 10161003	1/Prevax	29JUL2020	1	10
			2/1 Month	16SEP2020	29	10
		C4591001 1016 10161014	1/Prevax	30JUL2020	1	10
			2/1 Month	16SEP2020	29	10
		C4591001 1016 10161299	1/Prevax	23SEP2020	1	10
			2/1 Month	12NOV2020	29	10
		C4591001 1028 10281094	1/Prevax	01SEP2020	1	10
			2/1 Month	22OCT2020	29	10
		C4591001 1028 10281184	2/1 Month	03NOV2020	29	10
		C4591001 1028 10281211	1/Prevax	21SEP2020	1	10
			2/1 Month	18NOV2020	35	10
		C4591001 1028 10281248	1/Prevax	07OCT2020	1	10
			2/1 Month	23NOV2020	29	10
		C4591001 1042 10421003	1/Prevax	29JUL2020	1	10
			2/1 Month	17SEP2020	32	10
		C4591001 1042 10421111	1/Prevax	17AUG2020	1	10
			2/1 Month	07OCT2020	29	10
		C4591001 1042 10421112	1/Prevax	17AUG2020	1	10
			2/1 Month	09OCT2020	31	10

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1066 10661290	1/Prevax	22SEP2020	1	10
			2/1 Month	09NOV2020	29	10
		C4591001 1079 10791013	1/Prevax	30JUL2020	1	10
			2/1 Month	23SEP2020	36	10
		C4591001 1079 10791162	1/Prevax	20AUG2020	1	10
		C4591001 1080 10801055	1/Prevax	18AUG2020	1	10
			2/1 Month	07OCT2020	30	10
		C4591001 1083 10831001	1/Prevax	29JUL2020	1	10
			2/1 Month	18SEP2020	29	10
		C4591001 1085 10851003	1/Prevax	30JUL2020	1	10
		C4591001 1087 10871061	2/1 Month	29SEP2020	29	10
		C4591001 1089 10891015	1/Prevax	30JUL2020	1	10
			2/1 Month	21SEP2020	35	10
		C4591001 1092 10921083	1/Prevax	26AUG2020	1	10
			2/1 Month	15OCT2020	30	10
		C4591001 1093 10931203	1/Prevax	23OCT2020	1	10
		C4591001 1094 10941076	1/Prevax	01SEP2020	1	10
			2/1 Month	22OCT2020	29	10
		C4591001 1095 10951002	1/Prevax	30JUL2020	1	10
			2/1 Month	18SEP2020	29	10
		C4591001 1095 10951106	1/Prevax	07AUG2020	1	10
			2/1 Month	28SEP2020	32	10
		C4591001 1095 10951312	1/Prevax	20NOV2020	1	10
			2/1 Month	11JAN2021	32	10
		C4591001 1107 11071010	1/Prevax	30JUL2020	1	38
			2/1 Month	21SEP2020	35	67

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1109 11091030	1/Prevax	30JUL2020	1	10
		C4591001 1109 11091092	1/Prevax	01AUG2020	1	10
			2/1 Month	26SEP2020	35	10
		C4591001 1109 11091309	1/Prevax	22AUG2020	1	10
			2/1 Month	19OCT2020	40	10
		C4591001 1112 11121125	1/Prevax	17AUG2020	1	10
			2/1 Month	12OCT2020	34	16
		C4591001 1112 11121260	1/Prevax	06OCT2020	1	10
		C4591001 1116 11161322	1/Prevax	25SEP2020	1	10
		C4591001 1118 11181059	1/Prevax	19AUG2020	1	10
			2/1 Month	09OCT2020	29	10
		C4591001 1126 11261211	1/Prevax	17NOV2020	1	10
			2/1 Month	06JAN2021	29	10
		C4591001 1129 11291265	1/Prevax	03DEC2020	1	10
			2/1 Month	21JAN2021	31	10
		C4591001 1139 11391167	1/Prevax	11DEC2020	1	10
			2/1 Month	01FEB2021	34	10
		C4591001 1141 11411226	2/1 Month	10NOV2020	29	10
		C4591001 1146 11461342	2/1 Month	14DEC2020	29	10
		C4591001 1152 11521009	1/Prevax	12AUG2020	1	10
			2/1 Month	30SEP2020	29	10
		C4591001 1152 11521222	2/1 Month	14OCT2020	31	10
		C4591001 1168 11681088	1/Prevax	26AUG2020	1	10
			2/1 Month	20OCT2020	35	95
		C4591001 1168 11681090	2/1 Month	15OCT2020	29	10
		C4591001 1171 11711152	2/1 Month	20OCT2020	30	10

16.2.6.1 Listing of Assay Data – Subjects 12 Through 25 Years of Age

Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose/ Sampling Time Point	Date of Sample	Rel Day ^a	NT50 (Titer)
		C4591001 1171 11711221	2/1 Month	26OCT2020	29	10
		C4591001 1204 12041061	1/Prevax	08SEP2020	1	10
			2/1 Month	26OCT2020	29	10
		C4591001 1221 12211006	2/1 Month	04DEC2020	31	10
		C4591001 1223 12231113	1/Prevax	05SEP2020	1	10
			2/1 Month	27OCT2020	30	10
		C4591001 1231 12311556	1/Prevax	16AUG2020	1	10
			2/1 Month	09OCT2020	33	10

Abbreviation: NT50 = 50% neutralizing titer.

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

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (16:43)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adva_l001_ped

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
	W	Withdrawn from study
Cause of AE	CD	Concomitant drug treatment
	CND	Concomitant non-drug treatment
	O	Other
Outcome	F	Fatal
	N	Not recovered/not resolved
	R	Recovered/resolved
	RS	Recovered/resolved with sequelae
	RG	Recovering/resolving
	UNK	Unknown
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

16.2.7.1 Adverse Events Legend Page

Category	Abbreviation	Text
	IMMUN	Immune system disorders
	INFEC	Infections and infestations
	INJ&P	Injury poisoning and procedural complications
	INV	Investigations
	METAB	Metabolism and nutrition disorders
	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
	SOCCE	Social circumstances
	SURG	Surgical and medical procedures
	VASC	Vascular disorders
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/ae_legend		

16.2.7.2.1.1 Listing of Severe and Grade 4 Local Reactions – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)													
Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
					1	2	3	4	5	6	7		
12-15	C4591001 1009 10091288	1	04DEC2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	06DEC2020	3
	C4591001 1009 10091396	2	26JAN2021	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	28JAN2021	3
	C4591001 1013 10131845	1	03DEC2020	Pain at the injection site	Sev	Mod		N				04DEC2020	2
	C4591001 1057 10571438	1	04JAN2021	Pain at the injection site	N	Sev	Mild	Mild	N	N	N	07JAN2021	3
	C4591001 1066 10661408	1	08DEC2020	Pain at the injection site	Mod	Sev	Mild	Mild	N	N	N	11DEC2020	4
	C4591001 1091 10911406	2	28DEC2020	Pain at the injection site	Sev	Mod	Mild	N	N	N	N	30DEC2020	3
	C4591001 1091 10911428	1	16DEC2020	Pain at the injection site	Mod	Sev	Mild	Mild		N	N	19DEC2020	4
	C4591001 1140 11401359	1	23DEC2020	Pain at the injection site	N	Sev	N	N	N	N	N	24DEC2020	1
	C4591001 1140 11401376	1	29DEC2020	Pain at the injection site	Mild	Sev	Mild	Mild	N	N	N	01JAN2021	4
		2	20JAN2021	Pain at the injection site	Mild	Sev	Mod	Mild	N	N	N	23JAN2021	4
	C4591001 1142 11421340	2	28DEC2020	Pain at the injection site	Mod	Sev	Mild	N	N	N	N	30DEC2020	3
	C4591001 1142 11421369	2	15JAN2021	Pain at the injection site	Mod	Sev	N	N	N	N	N	16JAN2021	2
	C4591001 1147 11471320	2	27JAN2021	Pain at the injection site	Mod	Sev	Mod			Mild	Mild	06FEB2021	11

16.2.7.2.1.1 Listing of Severe and Grade 4 Local Reactions – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
					1	2	3	4	5	6	7		
16-25	C4591001 1150 11501124	2	10NOV2020	Pain at the injection site	Mod	Sev	Mod	Mild	N	N		13NOV2020	4
	C4591001 1150 11501250	1	29DEC2020	Pain at the injection site	Mod	Sev	Mild	N	N	N	N	31DEC2020	3
	C4591001 1152 11521697	1	18DEC2020	Pain at the injection site	Mod	Sev	Mild	Mild	N	N	N	21DEC2020	4
	C4591001 1156 11561249	1	16OCT2020	Redness (cu)		21						17OCT2020	1
				Redness (svt)	N	Sev		N	N	N	N		
	C4591001 1156 11561310	1	01DEC2020	Pain at the injection site	N	Sev	Mild	Mild		N		04DEC2020	3
	C4591001 1235 12351253	1	08JAN2021	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	10JAN2021	3
	C4591001 1008 10081782	2	30DEC2020	Redness (cu)			21	21				02JAN2021	2
				Redness (svt)	N	N	Sev	Sev	N	N			
	C4591001 1057 10571368	1	23NOV2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	24NOV2020	2
	C4591001 1090 10901043	2	24AUG2020	Pain at the injection site	Sev	Sev	Mild	N		N	Mild	01NOV2020	70
	C4591001 1120 11201130	2	03SEP2020	Pain at the injection site	Sev	Mod	Mild	Mild	Mild		N	07SEP2020	5
	C4591001 1125 11251243	1	08DEC2020	Pain at the injection site	Mild	Sev	Sev	Mild	N	N		11DEC2020	4
	C4591001 1142 11421316	1	24NOV2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	25NOV2020	2

16.2.7.2.1.1 Listing of Severe and Grade 4 Local Reactions – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
					1	2	3	4	5	6	7		
	C4591001 1150 11501152	2	23DEC2020	Pain at the injection site	Sev	Mod	Mild				N	25DEC2020	3
	C4591001 1162 11621019	1	03AUG2020	Pain at the injection site	N	Sev	N	N	N		N	04AUG2020	1
	C4591001 1194 11941069	1	20OCT2020	Pain at the injection site	Sev	Mod	Mild	N	N	N	N	22OCT2020	3
	C4591001 1194 11941091	1	22OCT2020	Pain at the injection site	Mod	Sev	Mild	Mild	Mild	N		26OCT2020	5
	C4591001 1205 12051079	1	11NOV2020	Pain at the injection site	Sev	Mod	Mild	N	N	N	N	13NOV2020	3
		2	02DEC2020	Pain at the injection site	Mod	Sev	Mod	Mild	Mild	Mild	Mild	09DEC2020	8
	C4591001 1212 12121007	2	17NOV2020	Pain at the injection site	Mod	Sev	Mild	Mild	N	N	N	20NOV2020	4
	C4591001 1217 12171012	1	23OCT2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	25OCT2020	3
	C4591001 1226 12261096	1	11AUG2020	Pain at the injection site	Mild	Sev	Mild	N	N	Mild	N	16AUG2020	6
	C4591001 1230 12301018	1	24SEP2020	Pain at the injection site	Sev	Sev	Mild	N	N	N	N	26SEP2020	3
	C4591001 1230 12301133	1	05OCT2020	Redness (cu)		2	21					07OCT2020	1
				Redness (svt)		N	Sev	N	N	N	N		
	C4591001 1231 12311018	2	27AUG2020	Pain at the injection site	N	Sev	Mild	Mild	Mild	N	N	31AUG2020	4

16.2.7.2.1.1 Listing of Severe and Grade 4 Local Reactions – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
					1	2	3	4	5	6	7		
	C4591001 1231 12311055	1	11AUG2020	Pain at the injection site	Mild	Sev	Mod	Mild	Mild	Mild	Mild	17AUG2020	7
	C4591001 1231 12311162	1	13AUG2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	15AUG2020	3
	C4591001 1247 12471033	2	15OCT2020	Pain at the injection site	N			Sev	Sev	N	N	19OCT2020	2
	C4591001 1247 12471199	1	06OCT2020	Redness (cu)	21	21						07OCT2020	2
				Redness (svt)	Sev	Sev		N			N		
				Swelling (cu)	21							06OCT2020	1
				Swelling (svt)	Sev	N		N			N		

Abbreviations: cu = caliper units; Dur = duration; Mod = moderate; N = none; Sev = severe; svt = severity.

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

b. The maximum measurable size for redness and swelling in the electronic diary (e-diary) was 21 caliper units. Redness and swelling exceeding 21 caliper units are reported as >21. Study sites recorded injection site redness or swelling in centimeters. These were converted to caliper units (1 caliper unit = 0.5 centimeters).

c. Stop date is the date the reaction was last reported.

d. Duration (days) was calculated as the difference from the start of the first reported reaction to resolution of the last reported reaction, inclusive. If the reaction continued beyond Day 7, the calculation includes all days from the last e-diary day until the date of resolution collected on the case report form. If the reaction was ongoing at the time of the subsequent vaccination, the end date/day for the reaction is the date/day that the next vaccine was administered, which was used for the duration calculation.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: .\nda2_unblinded\C4591001_BLA\adce_1004_sevlr_ped

16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
12-15	C4591001 1005 10051317	2	12NOV2020	Oral temperature (°C)	36.7	39.1	37.5	37.1	36.6	36.8	36.6	13NOV2020	1
	C4591001 1005 10051328	2	11NOV2020	Headache	N	Sev	N	N	N	N	N	12NOV2020	1
	C4591001 1006 10061189	1	01DEC2020	Oral temperature (°C)	37.1	39.9	36.8	36.9	35.8	37.1	37.4	02DEC2020	1
		2	22DEC2020	Oral temperature (°C)	37.3	39.3	37.3		37.1		36.9	23DEC2020	1
	C4591001 1006 10061220	2	28DEC2020	Headache	N	Sev	Mild	N	N		N	30DEC2020	2
	C4591001 1006 10061297	1	29DEC2020	Oral temperature (°C)	36.7	39.4	37.1	37.1	36.8	37.1	36.8	30DEC2020	1
				Fatigue	N	Sev	N	N	N	N	N	30DEC2020	1
	C4591001 1007 10071544	2	30DEC2020	Fatigue	N	Sev	N	N	N	N	N	31DEC2020	1
	C4591001 1007 10071546	2	30DEC2020	Chills	Sev	N	N	N	N	N	N	30DEC2020	1
	C4591001 1007 10071620	2	20JAN2021	Fatigue	N	Sev	Mod	Mod	Mod	Mod	Mod		
				Headache	N	Sev	Mod	Sev	Mild	Mod	Mod		
				Chills	N	Sev	N	Mod	N	N	Mod	27JAN2021	7
				New or worsened muscle pain	N	Sev	Mod	Sev	Mod	Mod	Mod		
				New or worsened joint pain	N	Sev	Mod	Sev	Mod	Mod	Mod		

16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1007 10071626	2	20JAN2021	Oral temperature (°C)	36.8	39.1	36.7	36.6		36.7	36.9	21JAN2021	1
	C4591001 1007 10071639	2	25JAN2021	Fatigue	Mild	Sev	Mild	N	N	N	N	27JAN2021	3
	C4591001 1007 10071642	1	04JAN2021	Fatigue	N	Sev	N	N	N	Mild	Mild	01FEB2021	28
	C4591001 1007 10071659	2	27JAN2021	Fatigue	N	Sev	Mild	N	N	N	N	29JAN2021	2
	C4591001 1008 10081802	1	17DEC2020	Oral temperature (°C)	36.6	39.1	36.3	36.4	35.7	36.9	35.8	18DEC2020	1
	C4591001 1008 10081809	1	18DEC2020	Headache	Sev			N	N		N	18DEC2020	1
	C4591001 1008 10081827	1	21DEC2020	Fatigue	N	Sev	N	N	N	N	N	22DEC2020	1
				Headache	N	Sev	N	N	N	N	N	22DEC2020	1
	C4591001 1008 10081846	2	11JAN2021	Oral temperature (°C)	37.3	39.3	36.4	36.2	36.1		36.2	12JAN2021	1
	C4591001 1008 10081908	2	27JAN2021	Oral temperature (°C)	36.8	39.7	37.3	37.1	36.9	37	37.1	28JAN2021	1
	C4591001 1009 10091220	1	19OCT2020	Fatigue	Mod		Sev	N		Mod	N	24OCT2020	6
	C4591001 1009 10091221	1	19OCT2020	New or worsened joint pain	Sev	N		N	N			19OCT2020	1
	C4591001 1009 10091288	2	23DEC2020	Chills	N	Sev	N	N	N	N	N	24DEC2020	1

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16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1009 10091310	2	29DEC2020	Headache	Mild	Sev		N	N	N		30DEC2020	2
	C4591001 1009 10091317	1	10DEC2020	Oral temperature (°C)	37.3	39	36.6	37.4	36.9	36.8	36.9	11DEC2020	1
				Headache	N	Sev	N	N	N	N	N	11DEC2020	1
	C4591001 1009 10091318	2	29DEC2020	Oral temperature (°C)	36.6	39	37.1	37	36.6	36.3	36.9	30DEC2020	1
	C4591001 1009 10091321	2	30DEC2020	Fatigue	N	Sev	Mild	N	N	N	N	01JAN2021	2
				Chills	N	Sev	N	N	N	N	N	31DEC2020	1
	C4591001 1009 10091326	1	11DEC2020	Headache	N	Sev	N	N	N	N	N	12DEC2020	1
	C4591001 1009 10091328	2	30DEC2020	Headache	N	Sev	N	Mild	N	N	N	02JAN2021	3
	C4591001 1009 10091355	2	08JAN2021	Headache		Sev	N	N	N		N	09JAN2021	1
	C4591001 1009 10091358	1	17DEC2020	Headache	N	N	N	N	N	N	Sev	23DEC2020	1
	C4591001 1009 10091361	1	17DEC2020	Fatigue	Mod	Mod	Sev	Mild	N	N	N	20DEC2020	4
				Headache	Mild	Sev	Mod	Mild	Mild	Mild	N	22DEC2020	6
	C4591001 1009 10091362	1	17DEC2020	Chills	Sev	Mod	N	N		Mod	Mild	24DEC2020	8
	C4591001 1013 10131841	1	02DEC2020	Fatigue		Sev			N			03DEC2020	1
				Headache		Sev			N			03DEC2020	1

16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1013 10131859	1	09DEC2020	Fatigue	N	Sev	N	N	N	N	N	10DEC2020	1
				Headache	N	Sev	N	N	N	N	N	10DEC2020	1
	C4591001 1013 10131866	2	06JAN2021	Fatigue	N	Sev	N	N	N	N		07JAN2021	1
				Chills	N	Sev	N	N	N	N		07JAN2021	1
	C4591001 1013 10131871	1	21DEC2020	Oral temperature (°C)	36.8	39	36.7	36.7	38.9		37.2	25DEC2020	4
				Fatigue	Mild	Sev	N	N	N		N	22DEC2020	2
	C4591001 1016 10161307	1	15OCT2020	Fatigue	Mod	Sev	Mild	Mod	Mild	N	Mild	22OCT2020	8
	C4591001 1016 10161326	2	10NOV2020	New or worsened joint pain	N	Sev	N	N		N	N	11NOV2020	1
	C4591001 1016 10161330	1	20OCT2020	Headache	N	N	N	N	N	N	Sev	27OCT2020	2
	C4591001 1016 10161373	2	27JAN2021	Headache	N	Sev	N	N	N	N	N	28JAN2021	1
				Chills	N	Sev	N	N	N	Mild	N	01FEB2021	5
	C4591001 1039 10391304	2	19JAN2021	Fatigue	N	Sev	N	N	N	N	N	20JAN2021	1
	C4591001 1039 10391318	2	29JAN2021	Fatigue	Mod		Sev	Mild	Mild		Mild	04FEB2021	7
	C4591001 1044 10441266	1	08DEC2020	Fatigue	Mod	Sev	N	Mild	N	N	N	11DEC2020	4
		2	28DEC2020	Chills		Sev	N	N	N	N	N	29DEC2020	1

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16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1044 10441291	2	06JAN2021	Oral temperature (°C)	36.1	39.6	37.2	36.1	36.9	36.4	36.6	07JAN2021	1
	C4591001 1044 10441300	2	18JAN2021	Fatigue		Sev	N	N	N	N		19JAN2021	1
	C4591001 1044 10441316	1	04JAN2021	Chills	N	Sev	N	N	N	N	N	05JAN2021	1
	C4591001 1044 10441322	2	27JAN2021	Headache	N	Sev	N	N	N	N	N	28JAN2021	1
	C4591001 1044 10441331	2	27JAN2021	Fatigue	N	Sev	N	N	N	N	N	28JAN2021	1
	C4591001 1044 10441343	2	29JAN2021	Oral temperature (°C)	37.3	39.5	37.7	37.5	36.2	36.6	36.5	30JAN2021	1
				Fatigue	Mod	Sev	Mod	Mod	Mod	Mod	Mod		
				Chills	N	Sev	Mod	N	N	N	N	31JAN2021	2
	C4591001 1044 10441355	2	29JAN2021	Headache	N	Sev	Mild	Mild	N	Mild	N	03FEB2021	5
	C4591001 1044 10441379	2	04FEB2021	Fatigue	Mild	Sev	N	N	N	N	N	05FEB2021	2
	C4591001 1057 10571382	1	08DEC2020	Oral temperature (°C)	35.9	39.1	36.9	36.8	37.4	37.1	36.5	09DEC2020	1
				Fatigue	N	Sev	N	N	N	N	N	09DEC2020	1
	C4591001 1057 10571411	2	06JAN2021	Fatigue	N	Sev	Mod	Mild	N	N	N	09JAN2021	3
	C4591001 1057 10571424	1	24DEC2020	Chills	N	Mod	Sev		Mod	Mod	Mild	01JAN2021	8

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16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1057 10571428	1	24DEC2020	Fatigue	N		N	N	N	Sev	Sev	31DEC2020	3
				Headache	N		N	N	N	Mod	Sev	31DEC2020	3
				Chills	N		N	N	Mod	Sev	N	29DEC2020	2
	C4591001 1057 10571438	2	25JAN2021	Oral temperature (°C)	36.8	39.2	36.6	36.7		36.9	37.1	26JAN2021	1
	C4591001 1057 10571451	1	12JAN2021	Oral temperature (°C)	36.5	39.2	38.1	37.1	37.3	36.3	36.6	14JAN2021	2
	C4591001 1066 10661408	2	28DEC2020	Headache	Mild	Sev	Mild			N	N	30DEC2020	3
	C4591001 1077 10771280	2	04JAN2021	Fatigue	Sev	Sev	N	N		N		05JAN2021	2
				New or worsened muscle pain	Sev	Sev	Mild	N		N		06JAN2021	3
	C4591001 1084 10841546	1	18DEC2020	Fatigue	Mild	Sev	Mild	Mild	N	N	N	21DEC2020	4
				Headache	Mild	Sev	Mild	Mild	N	N	Mild	24DEC2020	7
	C4591001 1084 10841571	1	30DEC2020	Fatigue		Mild		Mild		Sev		05JAN2021	6
	C4591001 1084 10841580	1	06JAN2021	Oral temperature (°C)	37.5	39.9	37.7	36.4	36.8	36.8	37	07JAN2021	1
	C4591001 1084 10841593	2	29JAN2021	Headache	N	Sev	Mild		N	N	N	31JAN2021	2
	C4591001 1091 10911457	1	29DEC2020	Fatigue	Sev	Mod	Mod	Sev	Mod	N	Mod	05JAN2021	8
		2	18JAN2021	Fatigue		Sev	Mod	Mod	Mild	N	N	22JAN2021	4

16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
				Headache		Sev	Mod	Mild	N	N	N	21JAN2021	3
	C4591001 1123 11231440	2	28DEC2020	Headache	N	Sev	N	N		N	N	29DEC2020	1
	C4591001 1123 11231442	1	09DEC2020	Oral temperature (°C)	39.7	33.4		33.4	34.6	34.1	34.1	09DEC2020	1
	C4591001 1123 11231461	2	05JAN2021	Oral temperature (°C)	37.8	39.3	37.6	37.1		36.4	36.7	06JAN2021	1
	C4591001 1123 11231475	2	11JAN2021	Oral temperature (°C)	36.8	39.4	36.8		36.8	37.5	37.1	12JAN2021	1
	C4591001 1123 11231481	2	12JAN2021	Headache	N	Sev	Mild	N	N		N	14JAN2021	2
	C4591001 1123 11231484	2	12JAN2021	Oral temperature (°C)		39.4	37.5	37.1	36.6		36.3	13JAN2021	1
				Headache		Sev	Mild	Mod	Mod		N	16JAN2021	4
	C4591001 1123 11231495	2	13JAN2021	Fatigue	Mod	Sev	N		N	N	N	14JAN2021	2
	C4591001 1123 11231513	1	30DEC2020	Headache	N	N	N	N	Sev	Mild	N	04JAN2021	2
	C4591001 1124 11241251	2	08JAN2021	Oral temperature (°C)	37.6	39	36.9	36.7			36.7	09JAN2021	1
	C4591001 1125 11251248	1	11DEC2020	Fatigue	Mod	Sev	Mod	Mod	Mild	Mild	Mild	17DEC2020	7
	C4591001 1125 11251252	1	16DEC2020	Fatigue		Sev	N					17DEC2020	1
	C4591001 1126 11261263	1	04DEC2020	Chills	N	Sev	N	N	N	N		05DEC2020	1

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16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1126 11261273	2	06JAN2021	Headache	N	Sev	Mild	Mild	N	N	N	09JAN2021	3
	C4591001 1126 11261281	1	16DEC2020	Headache	N	Mild	Sev	N	N	N	N	18DEC2020	2
	C4591001 1126 11261286	1	16DEC2020	Oral temperature (°C)	37.2	39	36.8	36.9	36.6	36.8	36.4	17DEC2020	1
	C4591001 1126 11261299	2	12JAN2021	New or worsened muscle pain	N	N	Sev	N	N	N	N	14JAN2021	1
	C4591001 1126 11261307	1	04JAN2021	Chills	N	Sev	N	N	N	N	N	05JAN2021	1
	C4591001 1126 11261309	1	04JAN2021	New or worsened muscle pain	N	Sev	N	N	N		N	05JAN2021	1
		2	25JAN2021	Fatigue	Mild	Sev	N	N	N	N	N	26JAN2021	2
				Chills	Mild	Sev	N	N	N	N	N	26JAN2021	2
	C4591001 1126 11261310	2	26JAN2021	Headache	N	Sev	N		N	N	N	27JAN2021	1
	C4591001 1126 11261315	1	06JAN2021	Oral temperature (°C)	36.9	39.3	36.3	36.8	36.6	36.9	36.8	07JAN2021	1
	C4591001 1126 11261324	2	28JAN2021	Oral temperature (°C)	36.4	39.2	36.6	36.2	36.5	36.3	35.8	29JAN2021	1
	C4591001 1131 11311290	2	20JAN2021	Fatigue	Mod	Sev		N	N	N	N	21JAN2021	2
				Headache	N	Sev		N	N	N	N	21JAN2021	1
	C4591001 1131 11311302	2	01FEB2021	Oral temperature (°C)	36.2	39.6	36.5	36.4	36.3		36.3	02FEB2021	1

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16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1139 11391155	2	28DEC2020	Fatigue	N	Sev	Mild	N	N	N	N	30DEC2020	2
	C4591001 1139 11391238	1	07JAN2021	Headache	Mild	Sev	Mod	Mild	Mild	N	Mild	14JAN2021	8
	C4591001 1140 11401328	2	05JAN2021	Oral temperature (°C)	36.7	39.5	37.1	37	37.1	37	37	06JAN2021	1
	C4591001 1140 11401329	2	05JAN2021	Oral temperature (°C)	36.8	40	36.9	36.5	36.6	36.7	36.7	06JAN2021	1
	C4591001 1140 11401343	1	21DEC2020	Headache	N	N	Sev	N	N	N	N	23DEC2020	1
	C4591001 1140 11401345	2	11JAN2021	Vomiting Oral temperature (°C)	N	N	Sev	N	N	N	N	23DEC2020	1
	C4591001 1140 11401352	2	13JAN2021	Headache	Mild	Sev	N	N	N	N	Mild	17FEB2021	36
	C4591001 1140 11401359	1	23DEC2020	Fatigue	N	Sev	N	N	N	N	N	24DEC2020	1
	C4591001 1140 11401378	2	20JAN2021	Fatigue	Mod	Sev		N		N	N	21JAN2021	2
	C4591001 1140 11401380	2	19JAN2021	Chills		Sev	N	N	N	N	N	20JAN2021	1
	C4591001 1140 11401391	2	28JAN2021	Headache			Sev	N	Mod	N	N	01FEB2021	3
	C4591001 1140 11401400	1	08JAN2021	Headache		N	N	N	Mod	N	Sev	20JAN2021	9

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16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1142 11421340	1	07DEC2020	Fatigue	N	Sev	N	N	N	N	N	08DEC2020	1
				Headache	N	Sev	N	N	N	N	N	08DEC2020	1
		2	28DEC2020	Headache	Mod	Sev	N	N	N	N	N	29DEC2020	2
	C4591001 1142 11421369	2	15JAN2021	Fatigue	Mod	Sev	Mild	N	N	N	N	17JAN2021	3
				Chills	Mild	Sev	Mild	N	N	N	N	17JAN2021	3
				New or worsened muscle pain	N	Sev	N	N	N	N	N	16JAN2021	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	16JAN2021	1
	C4591001 1142 11421375	1	22DEC2020	Fatigue	Sev	N		N	N	N	N	22DEC2020	1
	C4591001 1142 11421392	2	29JAN2021	Chills		Sev	N	N	N	N	N	30JAN2021	1
	C4591001 1147 11471277	2	28DEC2020	New or worsened muscle pain		N	N	N	N	Sev	Sev	07JAN2021	6
	C4591001 1147 11471285	2	04JAN2021	Fatigue						Sev	N	09JAN2021	1
	C4591001 1147 11471301	1	19DEC2020	Fatigue	N	Sev	Mild	N	N		N	21DEC2020	2
	C4591001 1147 11471312	2	09JAN2021	Fatigue	Mild	N	N	N	N	Sev	N	14JAN2021	6
	C4591001 1147 11471327	1	05JAN2021	Oral temperature (°C)	35.6	40.4	38	35.8	35.9		36.4	07JAN2021	2

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16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1147 11471334	2	27JAN2021	Chills	Sev	Mild	N	N	N	N	N	28JAN2021	2
	C4591001 1147 11471337	2	27JAN2021	Chills	N	Sev	N	N	N	N	N	28JAN2021	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	28JAN2021	1
	C4591001 1147 11471347	2	28JAN2021	Chills	N	Sev	Mild	N	N	N		30JAN2021	2
	C4591001 1150 11501198	2	30DEC2020	Fatigue	N	Sev						31DEC2020	1
	C4591001 1150 11501245	1	28DEC2020	Headache	N	Sev		N	N	N	N	29DEC2020	1
		2	19JAN2021	Headache	N	Sev	N	N	N	N	N	20JAN2021	1
	C4591001 1150 11501260	2	20JAN2021	Oral temperature (°C)	37.2	39.1	37.2	36.7	37.1	37	36.4	21JAN2021	1
	C4591001 1150 11501274	2	25JAN2021	New or worsened muscle pain		Sev	N					26JAN2021	1
				New or worsened joint pain		Sev	N					26JAN2021	1
	C4591001 1150 11501297	1	11JAN2021	Oral temperature (°C)	37.2	39.1	37.4	37.1	36.9	36.9	37.1	12JAN2021	1
		2	02FEB2021	Oral temperature (°C)	36.8	39.7	38.4	36.8		37.1		04FEB2021	2
				Fatigue	N	Sev	Mod	N		N		04FEB2021	2
				Chills	N	Sev	N	N		N		03FEB2021	1

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16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1150 11501299	1	12JAN2021	Chills	N	Sev	Mild	N	N	N	N	14JAN2021	2
		2	01FEB2021	Chills	N	Sev	Mild	N		N	N	03FEB2021	2
	C4591001 1152 11521619	2	22DEC2020	Oral temperature (°C)	36.7	39.3	37.9	37.2	36.9	37	36.8	23DEC2020	1
	C4591001 1152 11521670	2	30DEC2020	Chills	N	Sev	N	N	N	N	N	31DEC2020	1
	C4591001 1152 11521706	1	21DEC2020	Fatigue	Mod	Mod	Mild	N		Sev	Mild	27DEC2020	7
				Headache	N	N	N	N		Sev	Mod	27DEC2020	2
	C4591001 1156 11561340	2	19JAN2021	Fatigue	Sev	Mod		N	N	N		20JAN2021	2
	C4591001 1156 11561342	2	19JAN2021	Oral temperature (°C)	36.8	39.9	37.1	37	37	37	37	20JAN2021	1
	C4591001 1156 11561349	2	26JAN2021	Chills	N	Sev	N	N	N	N	N	27JAN2021	1
	C4591001 1156 11561356	1	07JAN2021	Fatigue	Mild	Sev	Mod	Mild	N	N	N	10JAN2021	4
				New or worsened muscle pain	N	Sev	N	N	N	N	N	08JAN2021	1
	C4591001 1156 11561358	2	29JAN2021	Fatigue	N	Sev	Mild	N	N	N	N	31JAN2021	2
	C4591001 1223 12231280	2	28JAN2021	Oral temperature (°C)		39.2	38.4					30JAN2021	2
	C4591001 1235 12351236	2	22DEC2020	New or worsened muscle pain	Mod	Sev	N	N	N		N	23DEC2020	2

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16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
16-25	C4591001 1235 12351249	1	15DEC2020	Headache	Sev	Mod	Mod		Sev	Mod	Mild	04JAN2021	21
		2	04JAN2021	Headache	Sev	Sev	Sev	Sev	Sev			09JAN2021	6
	C4591001 1235 12351254	2	28JAN2021	Fatigue		Sev	Mild	N	N	N	N	30JAN2021	2
				Chills		Sev	N	N	N	N	N	29JAN2021	1
	C4591001 1270 12701191	2	23DEC2020	Fatigue	N	Sev	Mild	N	N	N	N	25DEC2020	2
	C4591001 1270 12701207	2	05JAN2021	Oral temperature (°C)	37.4	39.5	37.4	37.1	37.2	36.8	37.4	06JAN2021	1
				Fatigue	N	Sev	Mod	Mod	N	Mod	N	10JAN2021	5
	C4591001 1270 12701220	2	08JAN2021	Oral temperature (°C)	37.2	39.1	37.4	37.1	36.2	36.4		09JAN2021	1
	C4591001 1270 12701239	2	28JAN2021	Oral temperature (°C)	36.2	39	36.1	36.1	36.3	36.1	36.2	29JAN2021	1
	C4591001 1001 10011125	1	04AUG2020	Fatigue	Mod	Mod	Sev	Mild			N	07AUG2020	4
				Headache	Mod	Mod	Sev	Mod			N	07AUG2020	4
				New or worsened muscle pain	N	N	Sev	N			N	06AUG2020	1
				New or worsened joint pain	N	Mild	Sev	N			N	06AUG2020	2
	C4591001 1005 10051024	2	31AUG2020	Fatigue		Sev	N	N	N		N	01SEP2020	1
	C4591001 1005 10051434	2	12JAN2021	Chills	N	Sev	N		N	N		13JAN2021	1

16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1005 10051442	1	22DEC2020	Fatigue	N	Sev	Mild	Mild	N	Mild	N	27DEC2020	5
	C4591001 1006 10061185	2	21DEC2020	Chills	N	Sev	N	N	N	N	N	22DEC2020	1
	C4591001 1006 10061192	2	22DEC2020	Headache	N	Sev	N	Mild	N	N	N	25DEC2020	3
	C4591001 1006 10061210	2	23DEC2020	Headache	N	Sev	N	N	N	N	N	24DEC2020	1
	C4591001 1006 10061246	1	10DEC2020	Fatigue	N	N	Sev	N	N	N	N	12DEC2020	1
	C4591001 1007 10071487	1	01DEC2020	Headache	N	Sev	Mild		N	N		03DEC2020	2
	C4591001 1007 10071503	1	03DEC2020	New or worsened muscle pain	Sev	Mod		N			N	04DEC2020	2
	C4591001 1009 10091028	2	31AUG2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	01SEP2020	1
	C4591001 1013 10131005	1	28JUL2020	Headache	N	N	N	N	Sev		N	01AUG2020	1
	C4591001 1013 10131059	2	25AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	27AUG2020	2
	C4591001 1015 10151035	2	04SEP2020	Fatigue		Sev	N	N	N	N	N	05SEP2020	1
				New or worsened muscle pain		Sev	N	N	N	N	N	05SEP2020	1
				New or worsened joint pain		Sev	N	N	N	N	N	05SEP2020	1

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16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1016 10161349	2	25NOV2020	Headache	Mod	Sev	Mild	N	N	N	N	27NOV2020	3
	C4591001 1044 10441244	2	14DEC2020	Fatigue	N	Sev	Mild	Mild	Mild	Mild	N	19DEC2020	5
				New or worsened muscle pain	N	Sev	Mild	N	N	N	N	16DEC2020	2
	C4591001 1044 10441245	2	14DEC2020	Fatigue		Sev	Mild	N	N		N	16DEC2020	2
	C4591001 1044 10441287	1	11DEC2020	Fatigue	Mod	Sev	Mild	Mild	N	Mild	Mild		
	C4591001 1071 10711039	2	04SEP2020	Headache	N	N	Mod	Sev		Mild	Mild	21SEP2020	16
	C4591001 1073 10731064	2	01SEP2020	Fatigue	Mod	Mod	Mod	Sev	N	N	N	04SEP2020	4
				Headache	N	Mod	N	Sev	N	N	N	04SEP2020	3
	C4591001 1073 10731083	2	02SEP2020	Fatigue	Mod	Sev	N	N	N		N	03SEP2020	2
				Chills	N	Sev	N	N	N		N	03SEP2020	1
	C4591001 1080 10801009	2	03SEP2020	Headache		Sev	Mod	N			N	05SEP2020	2
	C4591001 1082 10821036	1	04AUG2020	Headache	Mod	N	Mild	N	N	N	Sev	11AUG2020	8
		2	25AUG2020	Headache	N	Sev	Sev	N	N	N	Mod	31AUG2020	6
	C4591001 1090 10901043	2	24AUG2020	Headache	Mild	Sev	N	N		N	Mild	30AUG2020	7
				Chills	N	Sev	N	N		N	N	25AUG2020	1

16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1107 11071010	2	18AUG2020	Headache	Mod	N		Mod	Sev	Mod		23AUG2020	6
	C4591001 1107 11071055	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1109 11091020	2	18AUG2020	Headache	Mod	Sev	N	N		N	N	19AUG2020	2
	C4591001 1112 11121045	1	03AUG2020	Oral temperature (°C)	36.9	39	37	37.1	36.9	36.8	36.6	04AUG2020	1
	C4591001 1120 11201172	1	13AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	15AUG2020	2
	C4591001 1120 11201250	2	11SEP2020	Headache	N	Sev	N	N	N	N	N	12SEP2020	1
				New or worsened joint pain	N	Sev	N	N	N	Mod	Mild		
	C4591001 1125 11251243	1	08DEC2020	Fatigue	N	Mod	Sev	N	N	N		10DEC2020	2
				Headache	N	Sev	Sev	N	N	N		10DEC2020	2
	C4591001 1126 11261208	2	04DEC2020	Headache	N	Sev	N	N	N	N	N	05DEC2020	1
	C4591001 1129 11291261	2	14DEC2020	Headache	Sev	Sev	N	N	N	N	N	15DEC2020	2
	C4591001 1129 11291262	2	14DEC2020	Fatigue	Sev	Mild	Mild	N	N	N	N	16DEC2020	3
	C4591001 1135 11351088	2	28AUG2020	Fatigue	Mild	Sev	N	N	N	N	N	29AUG2020	2

16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1139 11391160	2	29DEC2020	Oral temperature (°C)	36.3	38.9	36.2			36.8		30DEC2020	1
	C4591001 1140 11401316	2	14DEC2020	Headache	Mild	Sev	N	N	N	N	N	15DEC2020	2
				Chills	N	Sev	N	N	N	N	N	15DEC2020	1
	C4591001 1140 11401320	2	23DEC2020	Fatigue	Mild	Sev	N	N	N	N	N	24DEC2020	2
	C4591001 1140 11401321	1	04DEC2020	Fatigue	Mod	Sev	Mod	N	N	N	N	06DEC2020	3
	C4591001 1140 11401322	2	23DEC2020	Fatigue	Mod	Sev	Mod	Mild	N			26DEC2020	4
				Headache	Mod	Sev	Mild	N	N			25DEC2020	3
	C4591001 1141 11411081	1	14AUG2020	Fatigue	N	Sev	N	N	N	N	N	15AUG2020	1
	C4591001 1142 11421336	2	23DEC2020	Headache		N	N	N	N	Sev	N	28DEC2020	1
	C4591001 1147 11471255	2	05DEC2020	Oral temperature (°C)	37.1	39.5	37.1	37.1	37.2	37.1	37	06DEC2020	1
				Chills	N	Sev	N	N	N	N	N	06DEC2020	1
	C4591001 1152 11521072	2	01SEP2020	Diarrhea	N	N	Sev	Mild		N	N	04SEP2020	2
	C4591001 1152 11521600	2	15DEC2020	Oral temperature (°C)	36.8	37.3	39	36.7	36.6	36.8	36.9	17DEC2020	1
	C4591001 1152 11521630	2	28DEC2020	Headache	N	Sev	N	N	N	N	N	29DEC2020	1

16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1152 11521632	1	07DEC2020	Chills	Mod	Sev	Mild	N			N	09DEC2020	3
		2	28DEC2020	Fatigue	N	Sev	Mild	N	N		N	30DEC2020	2
				Headache	N	Sev	Mild	N	N		N	30DEC2020	2
	C4591001 1156 11561299	1	11NOV2020	Fatigue	N	Mild	Mod	N	N	Sev	N	16NOV2020	5
	C4591001 1156 11561300	1	17NOV2020	Oral temperature (°C)	36.9	38.9	35.4	36.5	37.1		36.4	18NOV2020	1
	C4591001 1162 11621044	1	06AUG2020	Oral temperature (°C)			36.1			40	37.6	11AUG2020	1
				Fatigue			N			Sev	Sev	13AUG2020	3
				Headache			N			Sev	Sev	13AUG2020	3
				Chills			Mild			Sev	Mod	13AUG2020	6
				New or worsened muscle pain			N			Sev	N	11AUG2020	1
	C4591001 1162 11621080	2	02SEP2020	Headache	N	Sev	Mod	N	N	N		04SEP2020	2
				Chills	N	Sev	Mod	N	N	N		04SEP2020	2
	C4591001 1162 11621110	2	02SEP2020	Fatigue		Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1171 11711027	1	14AUG2020	Chills	N	Sev	N	N	N	N	N	15AUG2020	1
	C4591001 1194 11941062	2	11NOV2020	Fatigue	Mod	Sev	Mild	Mild	N	N	N	14NOV2020	4
	C4591001 1194 11941069	2	11NOV2020	Fatigue	Sev	Sev	Mild	N	N	N	N	13NOV2020	3

16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1195 11951100	1	18OCT2020	Vomiting	Sev	N	N		N	N	N	18OCT2020	1
	C4591001 1205 12051079	1	11NOV2020	Headache	Mild	Sev	N	N	Mild	N	Mod	18NOV2020	8
		2	02DEC2020	Headache	Mod	Sev	N	N	N	N	N	03DEC2020	2
				Chills	Mild	Sev	N	N	N	N	N	03DEC2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	03DEC2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	03DEC2020	1
	C4591001 1208 12081051	2	01DEC2020	Fatigue	Mod	Sev	Mod	N		N	N	03DEC2020	3
	C4591001 1212 12121007	2	17NOV2020	Oral temperature (°C)	36.9	39.5	37.5	36.9	36.8	36.6	37	18NOV2020	1
				Fatigue	Mod	Sev	Mod	N	N	N	N	19NOV2020	3
				New or worsened muscle pain	N	Sev	Mod	N	N	N	N	19NOV2020	2
	C4591001 1214 12141053	2	02DEC2020	Headache	N	N	N	N	N	N	Sev	08DEC2020	1
	C4591001 1217 12171053	1	06NOV2020	Fatigue	N	Sev		N	N	N	N	07NOV2020	1
		2	26NOV2020	Fatigue	N	Sev	N	N	N	N		27NOV2020	1
	C4591001 1223 12231057	1	01SEP2020	Headache	N	Sev	Mild	N	N	N	N	03SEP2020	2
	C4591001 1224 12241168	2	10DEC2020	Chills	Mod	Sev	N	N	N	N	N	11DEC2020	2

16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1224 12241171	1	23NOV2020	Fatigue	N	Sev	N	N	N	N	N	24NOV2020	1
				Headache	N	Sev	N	N	N	N	N	24NOV2020	1
	C4591001 1224 12241173	2	21DEC2020	New or worsened muscle pain	N	Sev		N	N		N	22DEC2020	1
	C4591001 1224 12241176	1	30NOV2020	Chills	N	Sev	N	N	N	N	N	01DEC2020	1
	C4591001 1224 12241178	1	30NOV2020	Fatigue	Mild	Sev	N	N	N	N	N	01DEC2020	2
				Chills	N	Sev	N	N	N	N	N	01DEC2020	1
		2	29DEC2020	Chills	Mild	Sev	Mild	N	N	N	N	31DEC2020	3
	C4591001 1226 12261001	2	25AUG2020	New or worsened muscle pain	Mod	Sev		N	N	N		26AUG2020	2
	C4591001 1226 12261096	1	11AUG2020	Fatigue	N	Sev	Mod	N	N	N	N	13AUG2020	2
				Headache	N	Sev	Mod	N	N	N	N	13AUG2020	2
				New or worsened muscle pain	N	Sev	Mild	N	N	N	N	13AUG2020	2
				New or worsened joint pain	N	Sev	Mild	Mild	N	N	N	14AUG2020	3
		2	01SEP2020	Fatigue	N	Sev	N	N	N	N	N	02SEP2020	1
	C4591001 1226 12261124	2	04SEP2020	Fatigue	N	Sev	N	N	N	N		05SEP2020	1
	C4591001 1229 12291065	1	30SEP2020	Chills	Mod	Mild	Mild	Mod	Sev	N	N	04OCT2020	5
		2	21OCT2020	Fatigue	Mild	N	Mod	N	N	Sev	N	26OCT2020	6

16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
				New or worsened muscle pain	N	Mild	N	N	N	Sev	Mod	27OCT2020	6
	C4591001 1230 12301018	1	24SEP2020	New or worsened muscle pain	Mod	Sev	N	N	N	N	N	25SEP2020	2
				New or worsened joint pain	N	Sev	N	N	N	N	N	25SEP2020	1
	C4591001 1230 12301094	1	01OCT2020	Headache	N	Sev	Sev	N	N	N	N	03OCT2020	2
	C4591001 1230 12301102	2	23OCT2020	Headache	N	Mod	N	Mod	N	Sev	N	28OCT2020	5
	C4591001 1231 12311018	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1231 12311055	2	01SEP2020	Oral temperature (°C)	36.7	39	37.2	36.7		36.5	36.6	02SEP2020	1
				Fatigue	N	Sev	N	N		Mod	N	06SEP2020	5
				Chills	N	Sev	N	N		N	N	02SEP2020	1
	C4591001 1231 12311164	2	02SEP2020	Fatigue	N	Sev	Mild	Mild	N	Mild	Mild	09SEP2020	7
				Chills	N	Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1231 12311266	2	02SEP2020	Oral temperature (°C)	37.4	39.1	37.9	36.2	36.4	36.3	36.2	03SEP2020	1
	C4591001 1231 12311281	2	04SEP2020	New or worsened muscle pain	Mild	Sev	N	N	N	N	N	05SEP2020	2
	C4591001 1231 12311306	1	15AUG2020	Headache	N	Mod	N	Sev	N	N	N	18AUG2020	3

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16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1231 12311368	2	04SEP2020	Oral temperature (°C)	36	39.1	39.2	35.8	35.9	36.6	35.9	06SEP2020	2
	C4591001 1231 12311432	1	15AUG2020	Headache	N	Sev	Mild	Mild	Mild	N	N	19AUG2020	4
	C4591001 1231 12311454	2	03SEP2020	Fatigue	Mild	Sev	N	N	N	N	N	04SEP2020	2
	C4591001 1231 12311463	1	15AUG2020	Fatigue	Mild	Mod	Mild	N	N	Sev	Mild	23AUG2020	9
	C4591001 1235 12351237	2	28DEC2020	New or worsened joint pain	N	Sev	N	N	N	N	N	29DEC2020	1
	C4591001 1235 12351241	2	28DEC2020	Headache	Mild	Sev	Mild	Mild	Mild	N	N	01JAN2021	5
	C4591001 1246 12461038	2	20OCT2020	Diarrhea	N	Sev	Mild			N	N	22OCT2020	2
	C4591001 1247 12471010	1	23SEP2020	Headache	Mild	Mild	Mod	N	Mod	Mild	Sev	29SEP2020	7
	C4591001 1247 12471033	2	15OCT2020	New or worsened muscle pain	N			Sev	Sev	N	N	19OCT2020	2
	C4591001 1247 12471121	1	30SEP2020	Oral temperature (°C)	39.2	39.8	39.1	39.2	39	38.8	38.9	06OCT2020	7
				Fatigue	Mod	Mod	Mod	Sev	Mod	Mod	Mod	06OCT2020	7
				Headache	Mod	Sev	Mod	Mod	Mod	Mild	Mod	06OCT2020	7
		2	21OCT2020	Oral temperature (°C)	38.9	40	39.6	39.3	38.2	38.9	38.8		
				Fatigue	Mod	Mod	Mod	Mod	Mod	Mod	Sev		

16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1247 12471145	2	22OCT2020	Headache		Mild	N		Sev	N	N	26OCT2020	4
	C4591001 1270 12701165	1	23NOV2020	Fatigue	N	Sev	N	N	N	N	N	24NOV2020	1

Abbreviations: Dur = duration; Mod = moderate; N = none; Sev = severe.

Note: Subject C4591001 1077 10771278 (13 years of age) experienced systemic events, including a temperature of 40.4°C, on the day of Dose 2. Since these events were recorded as adverse events and not in the electronic diary (e-diary), they do not appear in this listing.

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

b. Stop date is the date the event was last reported.

c. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive. If the event continued beyond Day 7, the calculation includes all days from the last e-diary day until the date of resolution collected on the case report form. If the event is ongoing at the time of the subsequent vaccination, the end date/day for the event is the date/day that the next vaccine was administered, which was used for the duration calculation.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_1004_sevse_ped

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
12-15	C4591001 1005 10051317	GENRL	Chills/ CHILLS	1	21OCT2020	2/2	2	Yes		NA/TC	R (22OCT2020)	N/N
	C4591001 1005 10051328	GASTR	Nausea/ NAUSEA	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
	C4591001 1005 10051424	GASTR	Nausea/ NAUSEA	2	08JAN2021	1/4	1	Yes		NA/TC	R (11JAN2021)	N/N
		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 1006 10061203	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

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		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
		NERV	Headache/ Headache	2	22DEC2020	1/3	2	Yes		NA/TC	R (24DEC2020)	N/N
	C4591001 1006 10061209	NERV	Syncope/ Syncope Vasovagal response	2	12MAR2021	80/1	1	No	O	NA/TCN	R (12MAR2021)	N/N
	C4591001 1006 10061245	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 10061266#	GENRL	Chills/ CHILLS	3	24FEB2021	1/3	2	Yes		NA/TC	R (26FEB2021)	N/N
	C4591001 1006 10061272	PSYCH	Anxiety/ Worsening of anxiety	1	23DEC2020	8/27	3	No	O	P/TC/TCN	R (18JAN2021)	Y/N
			Depression/ Worsening of Depression	1	23DEC2020	8/27	3	No	O	P/TC/TCN	R (18JAN2021)	Y/N
		INJ&P	Contusion/ Contusion left elbow	1	05FEB2021	52/C	1	No	O	NA	RG	N/N
	C4591001 1006 10061286	GENRL	Fatigue/ FATIGUE	2	16JAN2021	6/4	2	Yes		NA	R (19JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001100610061290	INJ&P	Concussion/Concussion	1	12JAN2021	22/C	2	No	O	NA/TC	RG	N/N
	C4591001100610061292	EAR	Cerumen impaction/ Earwax Impaction Left Ear	2	24JAN2021	13/5	2	No	O	NA/TCN	R (28JAN2021)	N/N
	C4591001100710071476	NERV	Syncope/ Vasovagal syncope without collapse*		30NOV2020	1/1	1	No	O	NA/TC/TCN	R (30NOV2020)	N/N
		NERV	Dizziness/ lightheadness after vaccination	2	21DEC2020	1/1	1	No	O	NA	R (21DEC2020)	N/Y
	C4591001100710071497	BLOOD	Lymphadenopathy/ swollen lymph node left axilla	2	25DEC2020	4/C	1	Yes		NA	RG	N/N
	C4591001100710071500	PSYCH	Sleep terror/ Night Terror	2	23DEC2020	2/1	1	No	O	NA	R (23DEC2020)	N/N
	C4591001100710071524	INFEC	Candida infection/ thrush	2	01FEB2021	35/2	2	No	CD	NA	R (02FEB2021)	N/N
	C4591001100710071533	MUSC	Myalgia/ abdominal muscle pain	2	06JAN2021	8/2	1	No	O	NA/TC	R (07JAN2021)	N/N
	C4591001100710071563	NERV	Dizziness/ lightheadness	1	14DEC2020	1/1	1	Yes		NA/TCN	R (14DEC2020)	N/Y

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1007 10071568	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	MUSC	Mobility decreased/ Altered Mobility of Left upper extremity	1	03JAN2021	19/C	2	No	O	NA/TC	RG	N/N
	C4591001 1007 10071581	INFEC	Appendicitis/ Appendicitis	2	11MAR2021	64/C	3	No	O	NA/TC	RG	Y/N
	C4591001 1007 10071584	GENRL	Injection site pain/ Soreness at injection site	2	07JAN2021	1/4	1	Yes		NA	R (10JAN2021)	N/Y
	C4591001 1007 10071585	SKIN	Urticaria/ hives; trunk, abdomen, back	2	16JAN2021	10/C	2	Yes		NA/TC	RG	N/N
	C4591001 1007 10071593	INJ&P	Ligament sprain/ left Ankle sprain	1	30DEC2020	3/17	2	No	O	NA/TCN	R (15JAN2021)	N/N
	C4591001 1007 10071613	GENRL	Injection site pain/ Pain at injection site	1	29DEC2020	1/1	1	Yes		NA	R (29DEC2020)	N/N
	C4591001 1007 10071615	BLOOD	Lymphadenopathy/ left axillary lymph node swelling	2	20JAN2021	2/4	1	Yes		NA	R (23JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1007 10071618	GENRL	Injection site pain/ Pain at injection nsite	1	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/Y
	C4591001 1007 10071620	GASTR	Abdominal pain/ Abdominal pain	2	21JAN2021	2/20	2	Yes		NA/TC	R (09FEB2021)	N/N
		NERV	Neuralgia/ generalized Functional neurologic pain	2	21JAN2021	2/C	2	No	O	NA/TC	RG	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/C	2	No	CD	NA/TC	RG	N/N
		SKIN	Dermatitis contact/ contact dermatitis bilateral arms	2	12FEB2021	24/C	1	No	O	NA/TC	RG	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/C	3	No	O	NA/TC	N	Y/N
	C4591001 1007 10071623	GASTR	Toothache/ teeth pain	2	27JAN2021	7/2	2	No	CND	NA/TC	R (28JAN2021)	N/N
	C4591001 1007 10071632	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

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		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
	C4591001 1007 10071634	RESP	Rhinorrhoea/ Rhinorrhea	2	18FEB2021	25/C	1	No	O	NA	RG	N/N
		NERV	Presyncope/ vasovagal response	2	22FEB2021	29/1	1	No	O	NA	R (22FEB2021)	N/N
	C4591001 1007 10071648	GENRL	Injection site pain/ Injection site pain	2	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/Y
	C4591001 1007 10071651	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/C	1	No	O	NA	RG	N/N
	C4591001 1008 10081928	SKIN	Urticaria/ urticaria multiple sites	1	10JAN2021	3/13	1	Yes		NA/TC	R (22JAN2021)	N/N
	C4591001 1009 10091220	INJ&P	Procedural pain/ POST SURGICAL PAIN, ORAL	2	20NOV2020	14/11	2	No	O	NA/TC	R (30NOV2020)	N/N
	C4591001 1009 10091221	MUSC	Arthralgia/ worsening right ankle pain	1	19OCT2020	1/1	3	No	O	NA/TCN	R (19OCT2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001100910091231	BLOOD	Lymphadenopathy/left swollen axillary lymph node	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
	C4591001100910091267	RESP	Rhinorrhoea/RUNNY NOSE	2	27DEC2020	6/6	1	No	O	NA/TC	R (01JAN2021)	N/N
	C4591001100910091294	MUSC	Arthralgia/bilateral shoulder pain	1	22DEC2020	16/3	1	No	O	NA	R (24DEC2020)	N/N
	C4591001100910091319	NERV	Headache/headache	2	22JAN2021	25/1	2	No	O	NA	R (22JAN2021)	N/N
	C4591001100910091323	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
	C4591001100910091334	RESP	Rhinorrhoea/runny nose	2	11JAN2021	12/1	1	No	O	NA	R (11JAN2021)	N/N
	C4591001100910091342	BLOOD	Lymphadenopathy/swollen cervical lymph nodes bilateral	2	31JAN2021	28/3	1	No	O	NA	R (02FEB2021)	N/N
	C4591001100910091361	INJ&P	Ligament sprain/sprained right thumb	1	02JAN2021	17/30	2	No	O	NA	R (31JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1009 10091363	NERV	Presyncope/ Vasovagal Reaction	1	09FEB2021	55/1	1	No	O	NA	R (09FEB2021)	N/N
	C4591001 1009 10091366	GENRL	Injection site pain/ Mild Injection Site Pain	2	26FEB2021	1/2	1	Yes		NA	R (27FEB2021)	N/N
	C4591001 1009 10091370	NERV	Headache/ headache	1	06JAN2021	20/1	3	No	O	NA/TC	R (06JAN2021)	N/N
	C4591001 1009 10091379	INJ&P	Fall/ GROUND LEVEL FALL	2	26FEB2021	44/1	2	No	O	NA	R (26FEB2021)	N/N
	C4591001 1009 10091380	INJ&P	Clavicle fracture/ Right Clavicle Fracture	1	18JAN2021	21/C	2	No	O	NA/TC	N	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	MUSC	Arthralgia/ RIGHT KNEE PAIN	1	10JAN2021	7/16	2	No	O	NA	R (25JAN2021)	N/N
	C4591001 1009 10091399	INJ&P	Foot fracture/ Left Fifth Metatarsal Fracture	2	23FEB2021	26/C	2	No	O	NA/TC	RG	N/N
	C4591001 1009 10091403	RESP	Rhinorrhoea/ runny nose	1	10JAN2021	3/4	1	Yes		NA	R (13JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1009 10091406	MUSC	Joint swelling/ Swilling in bilateral knees	1	25JAN2021	18/C	1	No	O	NA/TC	N	N/N
	C4591001 1009 10091410	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 1013 10131824	GENRL	Peripheral swelling/ SWELLING LEFT ARM	1	05DEC2020	5/2	1	Yes		NA	R (06DEC2020)	N/N
	C4591001 1013 10131839	INJ&P	Concussion/ CONCUSSION	2	01MAR2021	69/C	2	No	O	NA	RG	N/N
	C4591001 1016 10161316#	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 10161344	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 1039 10391246#	GENRL	Fatigue/ fatigue	3	27FEB2021	2/3	2	Yes		NA	R (01MAR2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			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
	C4591001 1039 10391250	PSYCH	Tic/ exacerbation of tic disorder	2	09JAN2021	13/C	1	No	O	NA	RG	N/N
	C4591001 1039 10391314	NEOPL	Fibroadenoma of breast/ Exacerbation of fibroadenoma of right breast	2	06FEB2021	10/C	1	No	O	NA	RG	N/N
	C4591001 1039 10391326	PSYCH	Depression/ Depression Exacerbation	1	26JAN2021	16/5	3	No	O	NA/TC/TCN	R (30JAN2021)	Y/N
	C4591001 1039 10391337	SKIN	Urticaria/ urticaria, both hands	2	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N
	C4591001 1044 10441275	MUSC	Myalgia/ myalgia	2	04JAN2021	7/1	1	Yes		NA/TC	R (04JAN2021)	N/N
	C4591001 1044 10441292	GENRL	Oedema peripheral/ Edema Toes (Bilateral)	1	17DEC2020	1/3	1	No	O	NA/TC	R (19DEC2020)	N/N
	C4591001 1044 10441304	SKIN	Rash/ rash	2	25FEB2021	38/3	1	No	O	NA/TC	R (27FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1044 10441335	SKIN	Acne/ Worsening of acne	2	27FEB2021	30/C	1	No	O	NA/TC	RG	N/N
	C4591001 1044 10441337	INJ&P	Humerus fracture/ Broken humerus (right arm)	1	10JAN2021	3/C	2	No	O	NA/TC	RG	N/N
	C4591001 1044 10441338	NEOPL	Skin papilloma/ Wart on second toe (left)	2	01FEB2021	4/7	1	No	O	NA/TC	R (07FEB2021)	N/N
	C4591001 1044 10441351	INJ&P	Muscle strain/ Left hip flexor strain	2	11FEB2021	11/17	2	No	O	NA/TC	R (27FEB2021)	N/N
	C4591001 1044 10441361	INJ&P	Concussion/ Concussion	1	23JAN2021	13/22	1	No	O	NA	R (13FEB2021)	N/N
	C4591001 1044 10441373	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 1057 10571451	INFEC	Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	1	13JAN2021	2/C	2	No	O	NA/TC	N	N/N
	C4591001 1066 10661422	SKIN	Rash/ rash on torso	1	24DEC2020	3/C	1	No	O	NA	N	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1077 10771278	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	GASTR	Oral mucosal blistering/ ORAL/BUCCAL BLISTERS	2	07JAN2021	4/4	2	Yes		NA	R (10JAN2021)	N/N
	C4591001 1084 10841556	INFEC	Ear infection/ L Ear infection	2	28JAN2021	11/9	2	No	O	NA/TC	R (05FEB2021)	N/N
	C4591001 1084 10841558	INJ&P	Ligament sprain/ left sprained ankle	2	27JAN2021	10/2	2	No	O	NA/TC	R (28JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1091 10911422	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 10911433	SKIN	Rash/ intermittent rash on wrist	1	19DEC2020	3/C	1	No	O	NA	N	N/N
	C4591001 1123 11231442	PSYCH	Depression/ Depression	1	23DEC2020	15/C	2	No	O	NA/TC	N	N/N
	C4591001 1123 11231448	GASTR	Diarrhoea/ Diarrhea	1	16DEC2020	6/3	1	Yes		NA	R (18DEC2020)	N/N
	C4591001 1123 11231472	INFEC	Tinea capitis/ Tinea capitis	1	01JAN2021	12/43	1	No	O	NA/TC	R (12FEB2021)	N/N
		SKIN	Acne/ worsening of acne vulgaris	1	07JAN2021	18/C	1	No	O	NA/TC	N	N/N
	C4591001 1123 11231507	PSYCH	Depression/ Worsening of Depression	2	19JAN2021	2/5	2	No	O	NA/TC	R (23JAN2021)	Y/N
	C4591001 1123 11231520	INFEC	Conjunctivitis/ Bilateral conjunctivitis	1	12JAN2021	14/6	1	No	O	NA/TC	R (17JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1123 11231523	EYE	Retinal haemorrhage/ INTRA RETINAL HEMORRHAGE OD	2	16FEB2021	22/C	2	No	O	NA	RG	N/N
	C4591001 1124 11241251	GENRL	Pyrexia/ Fever (102.2 degrees F)	2	09JAN2021	2/1	3	Yes		NA/TC	R (09JAN2021)	N/N
	C4591001 1125 11251248	GENRL	Fatigue/ Fatigue	2	05JAN2021	7/4	1	Yes		NA/TC	R (08JAN2021)	N/N
	C4591001 1126 11261246	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/C	1	No	O	NA	N	N/N
	C4591001 1126 11261254	IMMUN	Food allergy/ Allergic reaction, nuts	1	09DEC2020	7/1	2	No	O	NA/TC	R (09DEC2020)	N/N
	C4591001 1126 11261262#	GENRL	Injection site pain/ Left upper arm injection site pain	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
	C4591001 1126 11261263	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

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Radius fracture/ RIGHT DISTAL RADIUS TORUS FRACTURE	1	20DEC2020	17/32	2	No	O	NA/TC	R (20JAN2021)	N/N
	C4591001 1126 11261268	SKIN	Urticaria/ Facial Urticaria, worsening	1	18DEC2020	5/14	1	No	O	NA	R (31DEC2020)	N/N
		MUSC	Osteochondrosis/ Juvenile Osteochondrosis of bilateral fifth metatarsals	1	28DEC2020	15/C	2	No	O	NA/TC/TCN	RG	N/N
	C4591001 1126 11261275#	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#	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
	C4591001 1126 11261290	SKIN	Pityriasis rosea/ Worsening Pityriasis Rosea	1	23DEC2020	7/28	2	No	O	NA/TC	R (19JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1126 11261296	INJ&P	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
	C4591001 1126 11261301	GASTR	Nausea/ Nausea	1	24DEC2020	3/2	2	Yes		NA	R (25DEC2020)	N/N
	C4591001 1126 11261305#	GENRL	Injection site pain/ Left Upper Arm Injection Site Pain	3	24FEB2021	1/2	2	Yes		NA	R (25FEB2021)	N/N
	C4591001 1126 11261307	NERV	Migraine/ Migraine headache, worsening	1	24JAN2021	21/C	2	No	O	NA/TC	RG	N/N
	C4591001 1126 11261309	GASTR	Lip swelling/ Swollen lips	2	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
			Mouth swelling/ Swollen mouth	2	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	C4591001 1126 11261312	NERV	Headache/ Headache	1	17JAN2021	13/5	2	No	O	NA	R (21JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1126 11261314	SKIN	Rash/ Skin rash L side of neck to L scapula	2	01FEB2021	4/3	1	Yes		NA/TC	R (03FEB2021)	N/N
	C4591001 1131 11311280	NERV	Presyncope/ vasovagal reaction secondary to vaccine	1	17DEC2020	1/1	2	Yes		NA	R (17DEC2020)	N/N
	C4591001 1131 11311283	INFEC	Pilonidal cyst/ pilonidal cyst	1	29DEC2020	8/52	2	No	O	NA/TC	R (18FEB2021)	N/N
	C4591001 1131 11311287	RESP	Rhinorrhoea/ rhinorrhea	1	17JAN2021	20/18	1	No	O	NA	R (03FEB2021)	N/N
		BLOOD	Lymphadenopathy/ enlarge lymph nods- neck(bilateral)	2	27JAN2021	10/8	1	Yes		NA	R (03FEB2021)	N/N
	C4591001 1131 11311301	MUSC	Arthralgia/ sacroiliac joint pain	1	15JAN2021	5/C	2	No	O	NA	N	N/N
		INJ&P	Accident/ skiing accident	2	18FEB2021	14/C	2	No	O	NA/TC/TCN	RG	N/N
		INJ&P	Clavicle fracture/ broken collar bone	2	19FEB2021	15/C	1	No	O	NA/TC	RG	N/N
			Clavicle fracture/ right clavicle fracture	2	19FEB2021	15/C	2	No	O	NA/TC/TCN	RG	N/N
	C4591001 1139 11391225	INJ&P	Concussion/ concussion	2	01FEB2021	5/9	2	No	O	NA/TC	R (09FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1139 11391246	MUSC	Arthralgia/ Bilateral knee pain	1	11JAN2021	4/C	2	No	O	NA/TC	RG	N/N
	C4591001 1139 11391248	INJ&P	Muscle strain/ Muscle Strain	2	10MAR2021	41/C	1	No	O	NA	RG	N/N
	C4591001 1140 11401343	NERV	Migraine/ complex migraine	1	23DEC2020	3/1	3	Yes		NA/TC/TCN	R (23DEC2020)	N/N
	C4591001 1140 11401353	MUSC	Neck pain/ neck pain	2	03FEB2021	23/3	2	No	O	NA/TC	R (05FEB2021)	N/N
	C4591001 1140 11401357	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
			Injection site pain/ mild injection site pain	2	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/Y
	C4591001 1142 11421352	INJ&P	Patella fracture/ Fracture of left patella	2	31JAN2021	28/C	3	No	O	NA	RG	N/N
	C4591001 1142 11421385	BLOOD	Lymphadenopathy/ left supraclavicular lymph node swelling	1	07JAN2021	8/C	1	Yes		NA	RG	N/N
	C4591001 1142 11421394	NERV	Paraesthesia/ transient feeling of pins and needles to torso	1	18JAN2021	8/C	1	No	O	NA	RG	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1147 11471262	PSYCH	Generalised anxiety disorder/ Generalized anxiety disorder (worsening)	2	25JAN2021	22/C	1	No	O	NA/TC	N	N/N
	C4591001 1147 11471263	MUSC	Limb mass/ Arm mass	1	2020	1/C	1	No	O	NA/TC	N	N/N
	C4591001 1147 11471270#	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	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	SKIN	Acne/ Acne vulgaris (new diagnosis)	2	25JAN2021	17/C	1	No	O	NA/TC	N	N/N
	C4591001 1147 11471310	RESP	Nasal congestion/ Nasal congestion	1	02JAN2021	13/8	1	No	O	NA/TC	R (09JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		EAR	Ear pain/ Left ear pain	2	JAN2021	1/C	1	No	O	NA/TC	RG	N/N
	C4591001 1147 11471322	EAR	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	SKIN	Dermatitis contact/ Allergic reaction to surgical dressings.	2	09FEB2021	14/C	2	No	O	NA/TC	RG	N/N
	C4591001 1147 11471327	GENRL	Pyrexia/ Fever (104.7)	1	06JAN2021	2/3	4	Yes		P/TC	R (08JAN2021)	N/N
	C4591001 1147 11471331	INJ&P	Hand fracture/ Fracture of middle phalanx of left index finger	2	24FEB2021	28/C	1	No	O	NA	RG	N/N
	C4591001 1150 11501127	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
	C4591001 1150 11501129	INJ&P	Concussion/ Concussion	2	11JAN2021	63/60	2	No	O	NA	R (11MAR2021)	N/N
	C4591001 1150 11501130	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

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1150 11501131#	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
	C4591001 1150 11501132	GASTR	Diarrhoea/ Diarrhea	2	09NOV2020	1/2	2	Yes		NA	R (10NOV2020)	N/N
	C4591001 1150 11501182#	GENRL	Injection site pain/ Injection Site Pain	3	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/N
	C4591001 1150 11501193	PSYCH	Attention deficit hyperactivity disorder/ ADHD	1	DEC2020	1/C	1	No	O	NA	RG	N/N
	C4591001 1150 11501287	GENRL	Injection site pain/ Injection Site Pain	1	08JAN2021	2/1	1	Yes		NA/TC	R (08JAN2021)	N/N
	C4591001 1152 11521615	SKIN	Rash/ generalized rash upper body	1	03DEC2020	1/8	1	No	O	NA	R (10DEC2020)	N/N
	C4591001 1152 11521640	INFEC	Ear infection/ right ear infection, NFI	1	20DEC2020	14/7	2	No	O	NA/TC	R (26DEC2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1152 11521641	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	PSYCH	Depression/ Worsened Depression	1	26DEC2020	18/C	2	No	O	NA/TC	N	N/N
	C4591001 1152 11521683	BLOOD	Lymphadenopathy/ Swollen Lymph Node (Left Clavicle)	1	26DEC2020	12/C	1	No	O	NA	N	N/N
	C4591001 1152 11521704	BLOOD	Lymphadenopathy/ swollen lymph node left axilla	1	26DEC2020	6/10	2	Yes		NA	R (04JAN2021)	N/N
	C4591001 1152 11521706	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 11521740	INJ&P	Tooth fracture/ Chipped baby tooth	2	17FEB2021	22/1	1	No	O	NA	R (17FEB2021)	N/N
	C4591001 1152 11521749	GASTR	Abdominal pain/ ABDOMINAL CRAMPS	1	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
	C4591001 1152 11521756	GASTR	Diarrhoea/ Diarrhea	2	06FEB2021	6/3	1	No	O	NA	R (08FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1156 11561310	INFEC	Body tinea/ TINEA CORPORIS	1	08DEC2020	8/18	1	No	O	NA	R (25DEC2020)	N/N
	C4591001 1223 12231267	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
		MUSC	Myalgia/ generalized muscle aches	2	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
	C4591001 1223 12231271	GENRL	Injection site pain/ injection site pain	1	29JAN2021	22/4	1	Yes		NA	R (01FEB2021)	N/N
	C4591001 1223 12231281	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 12231286	NERV	Headache/ headache	2	05FEB2021	3/3	1	Yes		NA/TC	R (07FEB2021)	N/N
	C4591001 1270 12701205	INFEC	Subcutaneous abscess/ Subcutaneous Tissue Abcess Right Earlobe	1	19DEC2020	5/17	1	No	O	NA/TCN	R (04JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-25	C4591001127012701222	PSYCH	Suicidal ideation/ SUICIDAL IDEATION	2	16FEB2021	40/C	3	No	O	NA/TCN	N	Y/N
	C4591001127012701233	GASTR	Rectal prolapse/ Rectal Prolapse	2	22FEB2021	28/C	1	No	O	NA/TC	RG	N/N
	C4591001127012701236	PSYCH	Anxiety/ Anxiety	1	11JAN2021	6/C	1	No	O	NA	RG	N/N
	C4591001127012701237	MUSC	Musculoskeletal chest pain/ Rib pain on right side	1	10FEB2021	35/29	1	No	O	NA	R (10MAR2021)	N/N
	C4591001100110011125	NERV	Dizziness/ dizziness*		04AUG2020	1/1	1	Yes		NA	R (04AUG2020)	N/N
		NERV	Migraine/ migraine headache	1	05AUG2020	2/5	3	Yes		NA	R (09AUG2020)	N/N
		MUSC	Myalgia/ diffuse myalgias	1	06AUG2020	3/2	3	Yes		NA	R (07AUG2020)	N/N
		PSYCH	Disorientation/ disorientation	1	08AUG2020	5/2	1	No	O	NA	R (09AUG2020)	N/N
	C4591001100310031111	MUSC	Psoriatic arthropathy/ psoriatic arthritis	2	26SEP2020	38/C	2	Yes		NA/TC	N	Y/N
	C4591001100510051024	METAB	Decreased appetite/ DECREASED APPETITE	2	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1005 10051071#	GENRL	Chills/ CHILLS	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
			Fatigue/ FATIGUE	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
		NERV	Headache/ HEADACHE	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
	C4591001 1005 10051411	GASTR	Abdominal pain/ ABDOMINAL PAIN	2	29JAN2021	2/4	3	No	O	NA/TC	R (01FEB2021)	Y/N
	C4591001 1005 10051442	GENRL	Fatigue/ FATIGUE	2	14JAN2021	2/3	2	Yes		NA	R (16JAN2021)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	14JAN2021	2/4	1	Yes		NA	R (17JAN2021)	N/N
			Injection site swelling/ INJECTION SITE SWELLING (1 INCH)	2	14JAN2021	2/4	1	Yes		NA	R (17JAN2021)	N/N
		MUSC	Arthralgia/ GENERALIZED ARTHRALGIA	2	14JAN2021	2/3	1	Yes		NA	R (16JAN2021)	N/N
			Myalgia/ GENERALIZED MYALGIA	2	14JAN2021	2/3	2	Yes		NA	R (16JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		NERV	Headache/ WORSENING OF HEADACHE	2	14JAN2021	2/3	2	Yes		NA/TC	R (16JAN2021)	N/N
	C4591001 1006 10061031	INFEC	Oral fungal infection/ ORAL YEAST INFECTION	1	16AUG2020	4/11	2	No	O	NA/TC	R (26AUG2020)	N/N
	C4591001 1006 10061194	INFEC	Otitis externa/ Otitis Externa Left	2	15JAN2021	24/13	3	No	O	NA/TC/TCN	R (27JAN2021)	N/N
	C4591001 1006 10061194#	INJ&P	Mouth injury/ Oral laceration	2	15FEB2021	55/10	1	No	O	NA/TC/TCN	R (24FEB2021)	N/N
	C4591001 1006 10061202	NERV	Headache/ Headache	2	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	C4591001 1006 10061204	GENRL	Injection site bruising/ 1 MM BRUISING AT INJECTION SITE LEFT DELTOID	2	22DEC2020	1/25	1	Yes		NA	R (15JAN2021)	N/Y
	C4591001 1006 10061205	INJ&P	Foot fracture/ Left Great Toe Fracture	2	29JAN2021	37/C	2	No	O	NA/TC	RG	N/N
	C4591001 1006 10061208	GENRL	Pain/ Body Aches	2	24DEC2020	2/1	1	Yes		NA/TC	R (24DEC2020)	N/N
		NERV	Headache/ Headache	2	24DEC2020	2/1	1	Yes		NA/TC	R (24DEC2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		RESP	Oropharyngeal pain/ Sore Throat	2	24DEC2020	2/1	1	Yes		NA/TC	R (24DEC2020)	N/N
	C4591001 1006 10061215	INJ&P	Ligament sprain/ Knee sprain Right	1	10DEC2020	7/3	1	No	O	NA/TC	R (12DEC2020)	N/N
		MUSC	Arthralgia/ right shoulder pain	2	23JAN2021	2/C	3	No	O	NA/TC/TCN	RG	N/N
	C4591001 1006 10061216#	GENRL	Chills/ Chills	3	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
	C4591001 1006 10061240	GENRL	Injection site pain/ Injection site pain	2	05JAN2021	1/1	1	Yes		NA/TC	R (05JAN2021)	N/N
			Pyrexia/ Fever	2	05JAN2021	1/1	1	Yes		NA/TC	R (05JAN2021)	N/N
	C4591001 1006 10061246#	GENRL	Chills/ Chills	3	18FEB2021	2/3	2	Yes		NA/TC	R (20FEB2021)	N/N
		NERV	Headache/ Headache	3	18FEB2021	2/3	2	Yes		NA/TC	R (20FEB2021)	N/N
	C4591001 1007 10071154#	GENRL	Injection site pain/ Injection Site Arm Soreness	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
		GENRL	Chills/ chills	4	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N
			Pyrexia/ fever	4	02FEB2021	1/2	2	Yes		NA/TC	R (03FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1007 10071463#	EYE	Lacrimation increased/ Watery Eyes	3	03MAR2021	3/3	1	No	O	NA	R (05MAR2021)	N/N
	C4591001 1007 10071464	GASTR	Nausea/ nausea	1	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N
	C4591001 1007 10071470#	GENRL	Injection site pain/ Injection site pain	3	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
		NERV	Headache/ Headache	3	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
	C4591001 1007 10071493#	GENRL	Injection site pain/ Injection site pain	2	22FEB2021	63/3	1	Yes		NA	R (24FEB2021)	N/N
		GENRL	Fatigue/ Fatigue	3	23FEB2021	2/8	1	No	O	NA	R (02MAR2021)	N/N
		NERV	Headache/ Headache	3	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	C4591001 1007 10071502	GENRL	Injection site discomfort/ Weighted feeling in injection site arm	1	03DEC2020	1/3	1	Yes		NA	R (05DEC2020)	N/N
		INFEC	Cellulitis/ Right axillary cellulitis	2	01JAN2021	11/8	2	No	O	NA/TC	R (08JAN2021)	N/N
			Folliculitis/ Right axillary folliculitis	2	01JAN2021	11/8	2	No	O	NA	R (08JAN2021)	N/N
	C4591001 1007 10071510#	GENRL	Injection site pain/ Injection Site Pain	3	22FEB2021	1/2	1	Yes		NA/TC/TCN	R (23FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1007 10071538#	GENRL	Fatigue/ Fatigue	3	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
	C4591001 1007 10071548#	NERV	Presyncope/ Vasovagal response with venipuncture	2	11MAR2021	72/1	2	No	O	NA	R (11MAR2021)	N/N
	C4591001 1007 10071553	GENRL	Injection site pain/ injection site pain	1	10DEC2020	1/3	1	Yes		NA	R (12DEC2020)	N/Y
		NERV	Dizziness/ Lightheaded*		10DEC2020	1/1	1	No	O	NA	R (10DEC2020)	N/N
	C4591001 1007 10071553#	GENRL	Chills/ Chills	3	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
			Injection site pain/ Injection site pain	3	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
			Pain/ Body aches	3	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
		NERV	Headache/ Headache	3	18FEB2021	2/2	2	Yes		NA/TC	R (19FEB2021)	N/N
	C4591001 1008 10081776#	GENRL	Pain/ body aches	3	27FEB2021	2/3	2	Yes		NA/TC	R (01MAR2021)	N/N
			Pyrexia/ Fever	3	27FEB2021	2/3	2	Yes		NA/TC	R (01MAR2021)	N/N
		NERV	Headache/ Headache	3	27FEB2021	2/C	2	Yes		NA/TC	RG	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1009 10091261	INJ&P	Skin laceration/ left index finger laceration	2	10FEB2021	71/C	2	No	O	NA/TC/TCN	RG	N/N
	C4591001 1009 10091278	EAR	Ear pain/ ear ache	2	21JAN2021	31/8	1	No	O	NA	R (28JAN2021)	N/N
	C4591001 1009 10091285	GENRL	Injection site pain/ pain at injection site	2	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
		INFEC	Impetigo/ impetigo on face	2	12JAN2021	22/9	1	No	O	NA/TC	R (20JAN2021)	N/N
	C4591001 1009 10091286#	GENRL	Chills/ chills	3	06JAN2021	2/4	1	Yes		NA	R (09JAN2021)	N/N
			Pain/ body aches	3	06JAN2021	2/4	1	Yes		NA	R (09JAN2021)	N/N
		NERV	Headache/ Headache	3	06JAN2021	2/4	1	Yes		NA	R (09JAN2021)	N/N
	C4591001 1013 10131005	MUSC	Arthropathy/ CYST, WRIST, LEFT	2	SEP2020	14/	1	No	O	NA/TCN	R	N/N
	C4591001 1013 10131059	GENRL	Fatigue/ FATIGUE	2	26AUG2020	2/1	3	Yes		NA	R (26AUG2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	2	26AUG2020	2/1	2	Yes		NA	R (26AUG2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1015 10151006#	GENRL	Chills/ Chills	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
			Fatigue/ Fatigue	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
			Injection site pain/ Injection site pain	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
		INV	Body temperature increased/ Increased body temperature 99F	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
		NERV	Headache/ Headache	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
		GENRL	Fatigue/ Fatigue	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
			Injection site pain/ Injection site pain	4	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N
		MUSC	Myalgia/ Myalgias	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
	C4591001 1015 10151029#	GENRL	Injection site pain/ Injection site pain	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/Y
		GENRL	Injection site pain/ Injection site pain	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/Y
	C4591001 1015 10151035	BLOOD	Lymphadenopathy/ Swollen lymph node - left armpit axillary	2	04SEP2020	1/5	1	Yes		NA	R (08SEP2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001101610161003#	GASTR	Nausea/nausea	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
		GENRL	Chills/chills	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
			Pain/generalized body aches	3	03FEB2021	1/3	2	Yes		NA/TC	R (05FEB2021)	N/N
			Pyrexia/subjective fever	3	03FEB2021	1/3	1	Yes		NA/TC	R (05FEB2021)	N/N
	C4591001101610161028	SKIN	Dermatitis contact/Contact dermatitis	1	08AUG2020	6/8	2	No	O	NA/TC	R (15AUG2020)	N/N
	C4591001101610161349	SKIN	Rash erythematous/rash, top ten toes(red rash)	1	09NOV2020	4/C	1	No	O	NA	N	N/N
	C4591001101810181133	SURG	Wisdom teeth removal/Wisdom tooth extraction	1	20AUG2020	9/1	1	No	O	NA/TC	R (20AUG2020)	N/N
	C4591001103910391243#	GENRL	Injection site pain/Injection Arm Soreness	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
		GENRL	Fatigue/Fatigue	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
	C4591001103910391254#	GENRL	Injection site pain/injection site pain	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1044 10441234	RESP	Reflux laryngitis/ Laryngopharyngeal Reflux	2	DEC2020	1/C	1	No	O	NA/TC	RG	N/N
	C4591001 1044 10441237#	GENRL	Injection site pain/ injection site pain	3	25FEB2021	1/3	1	Yes		NA	R (27FEB2021)	N/N
		NERV	Headache/ headache	3	25FEB2021	1/4	1	Yes		NA/TC	R (28FEB2021)	N/N
	C4591001 1044 10441240	GASTR	Nausea/ nausea	1	09DEC2020	17/1	1	No	O	NA/TC	R (09DEC2020)	N/N
	C4591001 1044 10441242	NERV	Dizziness/ dizziness	1	24NOV2020	1/1	1	Yes		NA	R (24NOV2020)	N/N
	C4591001 1044 10441242#	SKIN	Eczema/ Worsening of eczema (face)	2	26FEB2021	74/3	1	No	O	NA/TC	R (28FEB2021)	N/N
	C4591001 1044 10441244	GENRL	Injection site pain/ injection site pain	1	24NOV2020	1/4	1	Yes		NA	R (27NOV2020)	N/N
	C4591001 1044 10441246	INFEC	Otitis media/ otitis media (Left ear)	1	02JAN2021	6/6	1	No	O	NA/TC	R (07JAN2021)	N/N
	C4591001 1054 10541012	GASTR	Diarrhoea/ diarrhea - 1 episode	2	17SEP2020	7/1	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1057 10571373#	GENRL	Injection site pain/ INJECTION SITE PAIN ON LEFT ARM	3	26JAN2021	1/3	2	Yes		NA	R (28JAN2021)	N/N
	C4591001 1066 10661396#	GENRL	Injection site pain/ pain at injection site	3	22DEC2020	1/3	1	Yes		NA	R (24DEC2020)	N/N
		GENRL	Fatigue/ fatigue	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
		MUSC	Myalgia/ muscle pain	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
		NERV	Headache/ headache	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
	C4591001 1071 10711039	GENRL	Fatigue/ FATIGUE	2	09SEP2020	6/13	2	Yes		NA	R (21SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	09SEP2020	6/13	1	Yes		NA	R (21SEP2020)	N/N
	C4591001 1081 10811012#	GENRL	Injection site pain/ pain at site of injection (left deltoid)	3	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N
		GASTR	Diarrhoea/ diarrhea (one episode)	3	02MAR2021	2/1	1	Yes		NA	R (02MAR2021)	N/N
		GENRL	Chills/ chills	3	02MAR2021	2/1	1	Yes		NA	R (02MAR2021)	N/N
			Pyrexia/ fever (101.9)	3	02MAR2021	2/2	1	Yes		NA/TC	R (03MAR2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Vax Grade	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	C4591001108310831001	INJ&P	Fall/ Fall	2	26AUG2020	6/1	2	No	O	NA	R (26AUG2020)	N/N
			Fibula fracture/ Fibula fracture	2	26AUG2020	6/C	2	No	O	NA/TC	RG	N/N
	C4591001108310831084	INJ&P	Meniscus injury/ Torn Meniscus-Right	1	17AUG2020	7/C	1	No	O	NA/TC/TCN	RG	N/N
	C4591001108710871064	INFEC	Tooth infection/ Wisdom Teeth Infection - Right lower quadrant	2	15JAN2021	136/15	2	No	O	NA/TC	R (29JAN2021)	N/N
	C4591001108710871078	RESP	Rhinitis allergic/ Worsening of Allergic Rhinitis	2	02FEB2021	156/C	1	No	O	NA/TC	N	N/N
	C4591001108710871078#	EYE	Blepharitis/ Blepharitis - Right Eye	2	19FEB2021	173/C	1	No	O	NA/TC	N	N/N
	C4591001108910891015	INFEC	Tonsillitis/ Tonsillitis	2	14SEP2020	28/1	2	No	O	NA/TCN	R (14SEP2020)	N/N
		PSYCH	Depression/ worsening depression	2	02NOV2020	77/30	2	No	O	NA/TC	R (01DEC2020)	N/N
	C4591001109010901038	RESP	Oropharyngeal pain/ sore throat	1	20AUG2020	17/4	2	No	O	NA	R (23AUG2020)	N/N
	C4591001109010901044#	GENRL	Fatigue/ Fatigue	3	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Injection site pain/ Injection site pain-right arm	3	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N
	C4591001 1090 10901201#	GENRL	Chills/ Chills	3	03MAR2021	1/3	2	Yes		NA	R (05MAR2021)	N/N
		MUSC	Myalgia/ Myalgia	3	03MAR2021	1/3	2	Yes		NA/TC	R (05MAR2021)	N/N
	C4591001 1091 10911067#	GENRL	Injection site pain/ injection pain	3	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/Y
		GENRL	Chills/ chills	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
			Fatigue/ fatigue	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
		MUSC	Arthralgia/ generalized arthralgia	4	03FEB2021	2/1	2	Yes		NA	R (03FEB2021)	N/N
			Myalgia/ Myalgia	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	C4591001 1091 10911088	GASTR	Crohn's disease/ Crohn's Disease	2	NOV2020	62/C	2	No	O	NA/TC	RG	N/N
	C4591001 1091 10911095#	MUSC	Myalgia/ myalgia	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	C4591001 1091 10911392	GENRL	Oedema peripheral/ left foot edema	1	01DEC2020	2/37	2	No	O	NA/TC	R (06JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		MUSC	Arthralgia/ right knee joint pain	2	24DEC2020	3/14	2	No	O	NA/TC	R (06JAN2021)	N/N
	C4591001 1091 10911398	RESP	Asthma/ asthma attack	1	14DEC2020	12/1	1	No	O	NA	R (14DEC2020)	N/N
	C4591001 1092 10921223	GENRL	Injection site pain/ Injection Site pain	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		NERV	Headache/ Headache	1	13OCT2020	2/1	2	Yes		NA	R (13OCT2020)	N/N
	C4591001 1095 10951055	REPRO	Cervical dysplasia/ ASCUS of cervix	1	10AUG2020	7/18	1	No	O	NA/TC	R (27AUG2020)	N/N
	C4591001 1095 10951106	MUSC	Arthralgia/ polyarthralgia	2	03SEP2020	7/2	1	No	O	NA	R (04SEP2020)	N/N
	C4591001 1095 10951308	PSYCH	Depression/ worsening of depression	2	DEC2020	1/C	1	No	O	NA/TC	N	N/N
	C4591001 1095 10951310	PSYCH	Attention deficit hyperactivity disorder/ ADHD diagnosed by Psychiatrist	2	25JAN2021	42/C	1	No	O	NA/TC	N	N/N
	C4591001 1095 10951317	GENRL	Fatigue/ Fatigue	2	15DEC2020	1/1	1	Yes		NA	R (15DEC2020)	N/Y

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Vax Grade	Cause of Vax Rel ^c	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	C4591001 1095 10951319	INJ&P	Joint dislocation/ L Patellar Dislocation	2	02JAN2021	6/C	1	No	O	NA/TC	RG	N/N
	C4591001 1096 10961031	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	14AUG2020	1/40		No	O	P	R (22SEP2020)	N/N
		RESP	Oropharyngeal pain/ Sore throat	1	05OCT2020	53/3	1	No	O	NA	R (07OCT2020)	N/N
		INFEC	Urinary tract infection/ urinary tract infection	1	22JAN2021	162/C	1	No	O	NA/TC	N	N/N
	C4591001 1107 11071010	INFEC	Vulvovaginal mycotic infection/ YEAST INFECTION VAGINAL	1	11AUG2020	13/7	1	No	O	NA/TC	R (17AUG2020)	N/N
	C4591001 1107 11071010#	GENRL	Pain/ BODYACHES	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
			Pyrexia/ FEVER	3	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
		NERV	Dizziness/ DIZZINESS	3	18FEB2021	1/1	1	Yes		NA	R (18FEB2021)	N/Y
			Headache/ HEADACHE	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	C4591001 1109 11091030	GENRL	Injection site erythema/ Injection Site Redness	1	30JUL2020	1/2	1	Yes		NA	R (31JUL2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1109 11091242#	GENRL	Fatigue/ FATIGUE	4	14FEB2021	2/C	1	Yes		NA	N	N/N
		NERV	Headache/ HEADACHE	4	14FEB2021	2/2	1	Yes		NA	R (15FEB2021)	N/N
	C4591001 1110 11101057#	GENRL	Injection site pain/ Pain at the site of injection.	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
	C4591001 1110 11101379	GENRL	Fatigue/ Fatigue	1	14NOV2020	2/1	2	Yes		NA	R (14NOV2020)	N/N
		MUSC	Arthralgia/ Joint Pain (Generalized)	1	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N
	C4591001 1112 11121078	INFEC	Pharyngitis streptococcal/ Strep Throat	1	24AUG2020	20/12	1	No	O	NA/TC	R (04SEP2020)	N/N
	C4591001 1112 11121125	INFEC	Tinea infection/ Ringworm	1	19AUG2020	3/31	2	No	O	NA/TC	R (18SEP2020)	N/N
	C4591001 1112 11121125#	MUSC	Myalgia/ Muscle Aches	3	26JAN2021	1/3	2	Yes		NA/TC	R (28JAN2021)	N/N
	C4591001 1114 11141008#	GENRL	Chills/ CHILLS	3	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N
			Injection site pain/ ARM PAIN AT INJECTION SITE	3	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1114 11141009#	GENRL	Fatigue/ FATIGUE	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
			Injection site pain/ Injection site pain	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	C4591001 1120 11201250	SKIN	Rash/ Rash torso and legs	1	27AUG2020	7/16	1	No	O	NA/TC	R (11SEP2020)	N/N
		NERV	Burning sensation/ Burning sensation in palm of left hand	2	16SEP2020	6/1	2	No	O	NA	R (16SEP2020)	N/N
	C4591001 1125 11251243	GENRL	Injection site pain/ Grade 3 Pain at Injection site	1	09DEC2020	2/1	3	Yes		P	R (09DEC2020)	N/N
		NERV	Headache/ Grade 3 Headache	1	09DEC2020	2/1	3	Yes		P/TC	R (09DEC2020)	N/N
	C4591001 1126 11261205	METAB	Decreased appetite/ Decreased appetite	1	23NOV2020	13/C	1	No	O	NA	RG	N/N
		PSYCH	Depressed mood/ Depressed mood	1	23NOV2020	13/C	1	No	O	NA	RG	N/N
	C4591001 1126 11261206#	GENRL	Injection site pain/ Pain, injection site	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
	C4591001 1126 11261207#	GENRL	Injection site pain/ Pain Injection Site	3	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1126 11261210#	GENRL	Injection site pain/ Left upper arm injection site pain	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	C4591001 1126 11261211#	GENRL	Chills/ Chills	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
			Injection site pain/ Injection site pain	3	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N
		NERV	Headache/ Headache	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	C4591001 1126 11261214#	GENRL	Chills/ Chills	3	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
			Injection site pain/ Injection site pain	3	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
			Malaise/ Malaise	3	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
	C4591001 1126 11261215#	GENRL	Injection site pain/ Left arm injection site pain	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
	C4591001 1126 11261220#	GENRL	Injection site pain/ Left upper arm injection site pain	3	17FEB2021	1/4	2	Yes		NA/TC	R (20FEB2021)	N/N
		NERV	Headache/ Headache	3	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
		GENRL	Chills/ Chills	3	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Pyrexia/ Fever	3	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
	C4591001 1126 11261223#	GENRL	Injection site pain/ Injection site pain	3	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
	C4591001 1126 11261224#	GENRL	Malaise/ Malaise	3	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N
	C4591001 1126 11261228#	GENRL	Injection site pain/ Injection Site Pain	3	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
		NERV	Headache/ Headache	3	12FEB2021	1/3	2	Yes		NA/TC	R (14FEB2021)	N/N
	C4591001 1126 11261236#	GENRL	Fatigue/ Fatigue	3	05FEB2021	1/4	2	Yes		NA	R (08FEB2021)	N/N
			Injection site pain/ Pain, injection site	3	05FEB2021	1/3	2	Yes		NA	R (07FEB2021)	N/N
	C4591001 1126 11261237#	GENRL	Injection site pain/ Injection Site Pain	3	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
	C4591001 1126 11261238#	GENRL	Injection site pain/ Injection site pain	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
	C4591001 1126 11261244#	BLOOD	Lymphadenopathy/ Lymph node swelling left armpit	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		GENRL	Injection site pain/ Left upper arm injection site pain	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
		GENRL	Chills/ Chills	3	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N
			Pyrexia/ Fever	3	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
	C4591001 1126 11261247#	GENRL	Injection site pain/ Left upper arm injection site pain	3	11FEB2021	1/3	2	Yes		NA/TC	R (13FEB2021)	N/N
		GENRL	Fatigue/ Fatigue	3	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
	C4591001 1126 11261248#	GENRL	Injection site pain/ Left upper arm injection site pain	3	11FEB2021	1/3	1	Yes		NA/TC	R (13FEB2021)	N/N
		MUSC	Myalgia/ Muscle aches, generalized	3	12FEB2021	2/2	2	Yes		NA/TC	R (13FEB2021)	N/N
		GENRL	Pyrexia/ Fever	3	13FEB2021	3/1	2	Yes		NA/TC	R (13FEB2021)	N/N
	C4591001 1126 11261259#	GASTR	Irritable bowel syndrome/ Worsening irritable bowel syndrome	2	14FEB2021	55/C	2	No	O	NA/TC/TCN	N	N/N
	C4591001 1126 11261260#	GENRL	Chills/ Chills	3	12FEB2021	2/1	2	Yes		NA	R (12FEB2021)	N/N
			Fatigue/ Fatigue	3	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		MUSC	Myalgia/ Muscle aches, generalized	3	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
		INFEC	Vulvitis/ Vulvitis	3	16FEB2021	6/7	2	No	O	NA/TC	R (22FEB2021)	N/N
		RENAL	Dysuria/ Dysuria	3	17FEB2021	7/6	2	No	O	NA	R (22FEB2021)	N/N
	C4591001 1126 11261261#	GENRL	Injection site pain/ Left upper arm injection site pain	3	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
	C4591001 1128 11281057	INFEC	Tonsillitis/ tonsillitis	2	19SEP2020	25/C	1	No	O	NA	N	N/N
	C4591001 1128 11281098	SKIN	Macule/ Erythematous, Macule upper anterior thigh	2	13SEP2020	10/27	2	No	O	NA/TC	R (09OCT2020)	N/N
		MUSC	Musculoskeletal chest pain/ chest wall pain	2	08OCT2020	35/5	1	No	O	NA	R (12OCT2020)	N/N
	C4591001 1128 11281098#	GENRL	Chills/ Chills	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
			Injection site pain/ Injection Site Soreness, Left Arm	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	C4591001 1129 11291097	INFEC	Urinary tract infection/ urinary tract infection	2	19DEC2020	110/3	2	No	O	NA/TC	R (21DEC2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1129 11291256#	EYE	Eye pain/ eye pain	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
		GENRL	Chills/ chills	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
		NERV	Headache/ headache	3	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
		MUSC	Back pain/ back pain muscular	3	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
		GENRL	Chills/ Chills	4	10MAR2021	2/2	1	Yes		NA	R (11MAR2021)	N/N
	C4591001 1129 11291260#	IMMUN	Anaphylactoid reaction/ Anaphylactoid Reaction	3	27JAN2021	3/1	4	Yes		P/TC	R (27JAN2021)	Y/N
	C4591001 1129 11291262	GASTR	Lip swelling/ lip swelling	1	23NOV2020	1/12	1	No	O	NA/TC	R (04DEC2020)	N/N
		GASTR	Aphthous ulcer/ worsening canker sore episode of lips	1	27NOV2020	5/8	2	Yes		NA/TC	R (04DEC2020)	N/N
	C4591001 1129 11291263#	GENRL	Injection site pain/ left deltoid injection site soreness	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	C4591001 1131 11311279	GENRL	Fatigue/ fatigue	2	12JAN2021	2/4	1	Yes		NA	R (15JAN2021)	N/N
			Injection site pain/ injection site pain	2	12JAN2021	2/3	1	Yes		NA	R (14JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1139 11391089	MUSC	Musculoskeletal discomfort/ Left Shoulder discomfort	1	26AUG2020	15/12	1	Yes		NA	R (06SEP2020)	N/N
	C4591001 1139 11391138	INFEC	Sinusitis/ sinusitis	2	08JAN2021	23/18	2	No	O	NA/TC	R (25JAN2021)	N/N
	C4591001 1140 11401321#	GENRL	Injection site pain/ Pain at injection site	3	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	C4591001 1141 11411006	MUSC	Back pain/ Back Pain	1	31JUL2020	1/10	3	Yes		NA/TC	R (09AUG2020)	N/N
		INFEC	Gingivitis/ Gum Infection	2	01DEC2020	103/72	1	No	O	NA/TC	R (10FEB2021)	N/N
	C4591001 1141 11411010	PSYCH	Anxiety/ Anxiousness	2	14SEP2020	14/93	2	No	O	NA/TCN	R (15DEC2020)	N/N
			Depressed mood/ Low Mood	2	14SEP2020	14/93	2	No	O	NA/TCN	R (15DEC2020)	N/N
	C4591001 1141 11411016#	GENRL	Injection site pain/ injection site pain	3	01FEB2021	1/4	1	Yes		NA	R (04FEB2021)	N/N
		GASTR	Nausea/ Nausea	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
		INV	Body temperature increased/ Elevated Body Temperature T. Max 100.1 F	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		MUSC	Myalgia/ Diffuse Myalgia in vaccinated arm	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
	C4591001 1141 11411021	GENRL	Injection site pain/ muscle soreness injection area	2	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
	C4591001 1141 11411029	MUSC	Arthralgia/ Arthralgias	2	17SEP2020	23/12	2	Yes		NA/TC/TCN	R (28SEP2020)	N/N
		PSYCH	Anxiety/ Anxiety Flare up	2	18SEP2020	24/C	1	Yes		NA/TC/TCN	N	N/N
	C4591001 1141 11411032#	GENRL	Fatigue/ Fatigue	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N
			Injection site pain/ Injection site pain left deltoid	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N
	C4591001 1141 11411053	PSYCH	Anxiety/ Worsening Anxiety	2	02DEC2020	99/62	2	No	O	NA/TC/TCN	R (01FEB2021)	N/N
			Depression/ Worsening depression	2	02DEC2020	99/62	2	No	O	NA/TC/TCN	R (01FEB2021)	N/N
	C4591001 1141 11411056	GENRL	Injection site hyperaesthesia/ Hyperesthesia left deltoid region on injection site	2	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/Y

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1141 11411067	MUSC	Plantar fasciitis/ worsening of plantar fasciitis left foot	2	14SEP2020	13/C	2	No	O	NA/TC	RG	N/N
	C4591001 1141 11411067#	GENRL	Fatigue/ fatigue	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
			Injection site pain/ injection site pain	3	21DEC2020	1/6	1	Yes		NA	R (26DEC2020)	N/N
		GENRL	Fatigue/ Fatigue	4	13JAN2021	1/4	2	Yes		NA	R (16JAN2021)	N/N
		NERV	Headache/ Headache (worse than typical)	4	13JAN2021	1/2	2	Yes		NA/TC	R (14JAN2021)	N/N
		GASTR	Nausea/ Nausea	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
		GENRL	Pyrexia/ Fever	4	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N
		MUSC	Myalgia/ Generalized Myalgia	4	14JAN2021	2/2	2	Yes		NA	R (15JAN2021)	N/N
		GENRL	Injection site pain/ Arm Pain (injection)	4	16JAN2021	4/2	1	Yes		NA	R (17JAN2021)	N/N
	C4591001 1141 11411070#	GENRL	Chills/ chills	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
			Fatigue/ fatigue	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
			Injection site pain/ injection site pain	3	23DEC2020	1/2	2	Yes		NA/TC	R (24DEC2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		GENRL	Pyrexia/ Fever	4	15JAN2021	2/1	1	Yes		NA/TC	R (15JAN2021)	N/N
	C4591001 1141 11411074#	GASTR	Abdominal discomfort/ Stomach discomfort	4	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N
		GENRL	Chills/ chills	4	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N
			Malaise/ Malaise	4	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N
			Pyrexia/ Fever (101 F)	4	25FEB2021	2/1	2	Yes		NA/TC	R (25FEB2021)	N/N
		MUSC	Myalgia/ myalgia	4	25FEB2021	2/1	3	Yes		NA/TC	R (25FEB2021)	N/N
		NERV	Headache/ Headache	4	25FEB2021	2/1	2	Yes		NA/TC	R (25FEB2021)	N/N
	C4591001 1142 11421045#	GENRL	Injection site pain/ injection site pain	3	26FEB2021	1/2	2	Yes		NA	R (27FEB2021)	N/N
		SKIN	Ecchymosis/ ecchymosis at left antecubital fossa	3	27FEB2021	2/C	1	No	O	NA	RG	N/N
	C4591001 1142 11421059#	GENRL	Injection site pain/ injection site pain	3	29DEC2020	1/2	2	Yes		NA	R (30DEC2020)	N/N
		GENRL	Fatigue/ fatigue	4	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
			Injection site pain/ injection site pain	4	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
			Pain/ body aches	4	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
	C4591001 1142 11421078#	GENRL	Injection site pain/ injection site pain	3	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
	C4591001 1147 11471258#	GENRL	Injection site pain/ Pain at injection site	3	26FEB2021	1/3	1	Yes		NA	R (28FEB2021)	N/N
	C4591001 1147 11471259	EYE	Eye pain/ Ocular pain, bilateral	2	05JAN2021	25/C	1	No	O	NA/TC	N	N/N
			Ocular hyperaemia/ Ocular redness, bilateral	2	05JAN2021	25/C	1	No	O	NA/TC	N	N/N
	C4591001 1147 11471272	INJ&P	Ligament sprain/ Sprained Ankle	2	14JAN2021	18/C	1	No	O	NA/TC	N	N/N
	C4591001 1149 11491335†	GENRL	Injection site pain/ mild pain at site of injection (right arm)	1	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N
	C4591001 1150 11501148#	GENRL	Injection site pain/ Pain at injection site	3	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N
		GENRL	Fatigue/ Fatigue	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
			Pain/ Generalized Body Aches	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
		NERV	Dizziness/ Dizziness	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1150 11501149#	GENRL	Injection site pain/ Pain at injection site	3	16FEB2021	1/3	2	Yes		NA	R (18FEB2021)	N/N
		GENRL	Fatigue/ Fatigue	3	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
			Pain/ Generalized Body Aches	3	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
		NERV	Headache/ Headache	3	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
	C4591001 1150 11501151#	GENRL	Injection site pain/ Pain at injection site	3	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
		GENRL	Fatigue/ Fatigue	3	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
	C4591001 1150 11501153#	GENRL	Injection site pain/ Pain at injection site	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
		PSYCH	Depression/ Worsening Depression- no prior hospitalizations for depression	3	02MAR2021	7/C	4	No	O	NA	RG	Y/N
	C4591001 1150 11501155#	GENRL	Injection site pain/ Pain at injection site	3	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
	C4591001 1150 11501158#	GENRL	Injection site pain/ Pain at injection site	3	18FEB2021	1/3	2	Yes		NA	R (20FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001115011501159#	GENRL	Injection site pain/ Pain at injection site	3	18FEB2021	1/3	2	Yes		NA	R (20FEB2021)	N/N
	C4591001115011501169#	GENRL	Injection site pain/ Injection Site Pain	3	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
	C4591001115011501170#	GENRL	Injection site pain/ Injection Site Pain	3	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N
	C4591001115211521024#	INJ&P	Upper limb fracture/ broken right arm	2	15JAN2021	136/C	2	No	O	NA/TC/TCN	N	N/N
	C4591001115211521591#	NERV	Headache/ Headache	3	12MAR2021	2/1	2	Yes		NA/TC	R (12MAR2021)	N/N
	C4591001115211521643	ENDO	Autoimmune thyroiditis/ Hashimoto's disease	2	12FEB2021	47/C	2	No	O	NA	N	N/N
	C4591001115611561300	GENRL	Pyrexia/ FEVER	1	18NOV2020	2/2	3	Yes		NA	R (19NOV2020)	N/N
	C4591001115611561329	NERV	Headache/ HEADACHE	2	07JAN2021	2/42	1	Yes		NA/TC	R (17FEB2021)	N/N
	C4591001116111611016	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	2	17JAN2021	60/C	1	No	O	NA	UNK	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001116211621019	INFEC	Sinusitis/sinus infection	2	06OCT2020	42/C	1	No	O	NA/TC	N	N/N
	C4591001116211621583	NERV	Headache/headache	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
	C4591001117011701022	GENRL	Pain/Exercise Induced Body Soreness	1	06SEP2020	21/2	1	No	O	NA/TC	R (07SEP2020)	N/N
		NERV	Headache/Headache	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	C4591001117111711027	INJ&P	Muscle strain/Lower back strain	2	18SEP2020	15/11	2	No	O	NA/TC	R (28SEP2020)	N/N
	C4591001118511851060#	GENRL	Fatigue/Fatigue	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
		NERV	Somnolence/Drowsiness	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
	C4591001119411941045#	GENRL	Injection site pain/Pain at injection site	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	C4591001119411941047#	GENRL	Injection site pain/Pain at injection site	3	26JAN2021	2/4	2	Yes		NA	R (29JAN2021)	N/N
		GENRL	Fatigue/Fatigue	4	15FEB2021	1/4	1	Yes		NA	R (18FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Injection site pain/ Pain at injection site	4	15FEB2021	1/5	2	Yes		NA	R (19FEB2021)	N/N
	C4591001 1194 11941067#	GENRL	Fatigue/ Fatigue	3	15JAN2021	1/6	3	Yes		NA	R (20JAN2021)	N/N
			Injection site pain/ Pain at injection site	3	15JAN2021	1/6	2	Yes		NA	R (20JAN2021)	N/N
			Injection site swelling/ Swelling at injection pain	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
		NERV	Headache/ Headache	3	16JAN2021	2/3	2	Yes		NA	R (18JAN2021)	N/N
		GENRL	Injection site pain/ Pain at injection site	4	05FEB2021	1/7	2	Yes		NA	R (11FEB2021)	N/N
	C4591001 1194 11941086#	GENRL	Injection site pain/ Pain at injection site	3	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N
		NERV	Headache/ Headache	3	29JAN2021	2/2	2	Yes		NA	R (30JAN2021)	N/N
		NERV	Headache/ Headache	4	19FEB2021	2/3	2	Yes		NA	R (21FEB2021)	N/N
	C4591001 1194 11941092#	GENRL	Injection site pain/ Pain at the injection site	3	27JAN2021	2/3	2	Yes		NA	R (29JAN2021)	N/N
	C4591001 1194 11941103#	GENRL	Injection site pain/ Pain at injection site	3	13JAN2021	2/4	1	Yes		NA	R (16JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1195 11951066#	GENRL	Chills/Chills	3	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
	C4591001 1195 11951100	GASTR	Vomiting/Emesis	1	18OCT2020	1/1	1	No	O	NA	R (18OCT2020)	N/N
	C4591001 1195 11951148	MUSC	Spinal disorder/cervical spine syndrome	1	02NOV2020	14/45	1	No	O	NA/TC	R (16DEC2020)	N/N
	C4591001 1195 11951148#	GENRL	Injection site pain/pain injection site	3	09FEB2021	2/7	2	Yes		NA	R (15FEB2021)	N/N
		GASTR	Nausea/Nausea	3	24FEB2021	17/2	1	Yes		NA/TC	R (25FEB2021)	N/N
	C4591001 1197 11971031	MUSC	Tenosynovitis/Tenosynovitis right forearm	2	15JAN2021	71/C	2	No	O	NA/TC	N	N/N
	C4591001 1197 11971031#	NERV	Headache/headache	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	C4591001 1203 12031026	NERV	Headache/headache	1	07NOV2020	19/1	2	No	O	NA/TC	R (07NOV2020)	N/N
		GASTR	Inguinal hernia/inguinal hernia left	1	09NOV2020	21/103	2	No	O	NA/TC/TCN	R (19FEB2021)	Y/N
	C4591001 1203 12031026#	NERV	Headache/systemic vaccination reaction headache	3	01MAR2021	1/1	2	Yes		NA/TC	R (01MAR2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1203 12031047#	GENRL	Injection site pain/ tenderness at injection site	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		GENRL	Malaise/ Malaise	4	03MAR2021	1/3	2	Yes		NA	R (05MAR2021)	N/N
		MUSC	Arthralgia/ Arthralgia	4	03MAR2021	1/3	2	Yes		NA	R (05MAR2021)	N/N
		GENRL	Pyrexia/ Fever	4	04MAR2021	2/2	1	Yes		NA/TC	R (05MAR2021)	N/N
	C4591001 1213 12131003#	GENRL	Injection site pain/ PAIN AT INJECTION SITE	3	08JAN2021	1/2	2	Yes		NA	R (09JAN2021)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	3	08JAN2021	1/2	2	Yes		NA	R (09JAN2021)	N/N
		GENRL	Injection site pain/ PAIN AT INJECTION SITE	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N
		NERV	Headache/ HEADACHE	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N
		SKIN	Hyperhidrosis/ SWEATING	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N
	C4591001 1213 12131018#	GENRL	Injection site pain/ PAIN AT INJECTION SITE	3	12JAN2021	1/2	2	Yes		NA	R (13JAN2021)	N/N
		NERV	Headache/ HEADACHE	3	12JAN2021	1/2	2	Yes		NA	R (13JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	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	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
		NERV	Headache/ HEADACHE	4	01FEB2021	1/3	3	Yes		NA	R (03FEB2021)	N/N
	C4591001 1214 12141012#	GENRL	Injection site pain/ Pain at injection site	3	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N
		GENRL	Fatigue/ Fatigue	3	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N
		NERV	Headache/ Headache	3	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N
		GENRL	Injection site pain/ pain at injection site	4	24FEB2021	1/4	2	Yes		NA	R (27FEB2021)	N/N
		GENRL	Fatigue/ Fatigue	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N
		NERV	Headache/ Headache	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N
	C4591001 1214 12141022#	GENRL	Injection site pain/ pain at injection site	3	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
		GENRL	Injection site pain/ pain at injection site	4	22FEB2021	1/4	2	Yes		NA	R (25FEB2021)	N/N
		GENRL	Fatigue/ fatigue	4	23FEB2021	2/2	2	Yes		NA	R (24FEB2021)	N/N
	C4591001 1214 12141027#	GENRL	Injection site pain/ pain at injection site	3	01FEB2021	1/2	3	Yes		NA	R (02FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		GENRL	Fatigue/ fatigue	4	23FEB2021	1/2	2	Yes		NA/TC	R (24FEB2021)	N/N
		MUSC	Pain in extremity/ arm pain	4	23FEB2021	1/2	2	Yes		NA/TC	R (24FEB2021)	N/N
	C4591001 1214 12141053#	MUSC	Pain in extremity/ Arm Pain	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		MUSC	Pain in extremity/ Arm Pain	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		GENRL	Fatigue/ Fatigue	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	C4591001 1217 12171032#	GENRL	Injection site pain/ Injection pain (Arm pain)	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
		GENRL	Fatigue/ Lassitude	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
			Injection site pain/ Injection pain(arm pain)	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	C4591001 1217 12171041#	GENRL	Injection site pain/ arm pain (injection pain)	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
		GENRL	Pyrexia/ 38 C Fever	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	C4591001 1223 12231005#	GENRL	Injection site pain/ injection site pain	3	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1223 12231008#	GENRL	Fatigue/ fatigue	4	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
		MUSC	Back pain/ back pain	4	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
	C4591001 1223 12231025#	GENRL	Injection site pain/ injection site pain	3	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	C4591001 1223 12231036#	GENRL	Fatigue/ fatigue	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	C4591001 1223 12231057	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
			Pyrexia/ Fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		NERV	Headache/ Headache	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	C4591001 1223 12231073	GASTR	Nausea/ nausea	2	04OCT2020	13/2	2	No	O	NA	R (05OCT2020)	N/N
		NERV	Dizziness/ Dizziness	2	04OCT2020	13/2	2	No	O	NA	R (05OCT2020)	N/N
	C4591001 1223 12231073#	GENRL	Chills/ chills	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		NERV	Headache/ headache	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	C4591001 1224 12241168	GENRL	Pyrexia/ Fever - 101.0F	2	18DEC2020	9/1	1	Yes		NA/TC	R (18DEC2020)	N/N
		SKIN	Rash/ Rash - bilateral upper arms	2	18DEC2020	9/1	1	Yes		NA/TC	R (18DEC2020)	N/N
	C4591001 1226 12261049	GENRL	Pyrexia/ fever (38 C)	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
		NERV	Headache/ Headache	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	C4591001 1226 12261082	GASTR	Nausea/ nausea	1	19AUG2020	9/1	1	No	O	NA/TC	R (19AUG2020)	N/N
		MUSC	Torticollis/ torticollis	1	24AUG2020	14/1	1	No	O	NA/TC	R (24AUG2020)	N/N
	C4591001 1226 12261100#	GENRL	Fatigue/ Fatigue	3	22JAN2021	1/3	2	Yes		NA/TC	R (24JAN2021)	N/N
			Injection site pain/ Pain at injection site	3	22JAN2021	1/3	2	Yes		NA/TC	R (24JAN2021)	N/N
		GENRL	Pyrexia/ Fever 39 C	4	11FEB2021	2/3	2	Yes		NA/TC	R (13FEB2021)	N/N
	C4591001 1226 12261124	MUSC	Pain in extremity/ Pain in legs	1	19AUG2020	8/3	2	No	O	NA/TC	R (21AUG2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1226 12261126	MUSC	Back pain/ acute low back pain	1	20AUG2020	9/C	2	No	O	NA/TC	RG	N/N
	C4591001 1226 12261126#	GENRL	Fatigue/ tiredness	3	02FEB2021	2/3	2	Yes		NA	R (04FEB2021)	N/N
			Injection site pain/ pain at the injection site	3	02FEB2021	2/3	2	Yes		NA/TC	R (04FEB2021)	N/N
		MUSC	Myalgia/ muscle pain	3	02FEB2021	2/3	2	Yes		NA/TC	R (04FEB2021)	N/N
		GENRL	Injection site pain/ Pain at the injection site	4	22FEB2021	1/4	2	Yes		NA/TC	R (25FEB2021)	N/N
			Injection site swelling/ Swelling at the injection site	4	22FEB2021	1/4	2	Yes		NA/TC	R (25FEB2021)	N/N
		GENRL	Chills/ Chills	4	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
		INV	Body temperature increased/ Increased body temperature 37.6 C	4	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
		MUSC	Arthralgia/ Joint pain	4	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
	C4591001 1226 12261144	NERV	Headache/ Headache	1	27AUG2020	16/1	1	No	O	NA	R (27AUG2020)	N/N
		NERV	Headache/ Headache	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1226 12261158#	GENRL	Chills/ Chills	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
			Injection site pain/ Pain at the injection site	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
		MUSC	Myalgia/ Myalgia	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
		NERV	Headache/ Headache	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
		GENRL	Chills/ chills	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
			Pain/ body pain	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
	C4591001 1226 12261172#	GENRL	Chills/ chills	3	30JAN2021	1/2	1	Yes		NA/TC	R (31JAN2021)	N/N
		NERV	Headache/ headache	3	30JAN2021	1/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	C4591001 1226 12261207#	GENRL	Pyrexia/ Fever 38 C	4	20FEB2021	1/3	1	Yes		NA/TC	R (22FEB2021)	N/N
	C4591001 1226 12261230#	GENRL	Pain/ body pain	3	06FEB2021	2/4	1	Yes		NA/TC	R (09FEB2021)	N/N
	C4591001 1226 12261238#	GENRL	Injection site pain/ pain at the injection site	4	21FEB2021	2/1	1	Yes		NA	R (21FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1226 12261251#	GASTR	Nausea/ Nausea	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
		GENRL	Injection site pain/ Pain at injection site	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
		GENRL	Injection site pain/ pain at the injection site	4	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N
		GASTR	Nausea/ Nausea	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	C4591001 1230 12301057#	MUSC	Myalgia/ New onset of muscle pain.	3	29JAN2021	2/4	3	Yes		NA/TC	R (01FEB2021)	N/N
		GENRL	Injection site pain/ Pain at injection site.	3	07FEB2021	11/14	2	Yes		NA	R (20FEB2021)	N/N
		GENRL	Peripheral swelling/ Swelling left upper arm.	4	17FEB2021	2/4	2	Yes		NA	R (20FEB2021)	N/N
		MUSC	Myalgia/ New onset of muscle pain.	4	17FEB2021	2/4	2	Yes		NA	R (20FEB2021)	N/N
		MUSC	Arthralgia/ New onset of joint pain left upper wrist	4	19FEB2021	4/15	3	Yes		NA/TC	R (05MAR2021)	N/N
	C4591001 1230 12301114#	GENRL	Chills/ Chills	3	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N
		MUSC	Myalgia/ Muscle pain in upper arms and legs.	3	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001123112311141	INFEC	Genital herpes/exacerbated genital herpes	2	27SEP2020	26/9	1	No	O	NA/TC/TCN	R (05OCT2020)	N/N
	C4591001123112311164	GASTR	Abdominal pain/Abdominal pain	2	02SEP2020	1/2	3	No	O	NA/TC/TCN	R (03SEP2020)	N/N
	C4591001123112311191	INFEC	Cystitis/Cystitis	1	09OCT2020	57/3	1	No	O	NA/TC	R (11OCT2020)	N/N
	C4591001123112311199	INFEC	Genital herpes simplex/Genital herpes simplex type 2	2	16SEP2020	14/13	1	No	O	NA/TC	R (28SEP2020)	N/N
	C4591001123112311229	CARD	Tachycardia/tachycardia	2	06OCT2020	33/39	2	No	O	NA	R (13NOV2020)	N/N
	C4591001123112311281	INFEC	Appendicitis/acute appendicitis	2	18SEP2020	15/19	3	No	O	NA/TC/TCN	R (06OCT2020)	Y/N
		INV	Electrocardiogram QT prolonged/QT interval prolongation	2	18SEP2020	15/1	1	No	O	NA	R (18SEP2020)	N/N
	C4591001123112311306	GENRL	Chest pain/Self-limited oppressive chest pain	1	02SEP2020	19/1	1	No	O	NA	R (02SEP2020)	N/N
	C4591001123112311387	INJ&P	Exposure during pregnancy/Drug Exposed Pregnancy	2	07NOV2020	65/C		No	O	NA	UNK	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		INFEC	Urinary tract infection/ Complicated Urinary Tract Infection	2	04JAN2021	123/15	3	No	O	NA/TC	R (18JAN2021)	Y/N
	C4591001 1231 12311388	NERV	Headache/ headache	1	16AUG2020	2/8	1	No	O	NA	R (23AUG2020)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	1	18AUG2020	4/7	1	Yes		NA	R (24AUG2020)	N/N
		MUSC	Arthralgia/ ARTHRALGIA	1	21AUG2020	7/4	1	No	O	NA	R (24AUG2020)	N/N
		SURG	Tooth extraction/ Programmed extraction of the right third molar	2	26SEP2020	24/1	1	No	CND	NA/TC/TCN	R (26SEP2020)	N/N
	C4591001 1231 12311436	GASTR	Diarrhoea/ diarrhea	2	30SEP2020	28/2	1	No	O	NA/TCN	R (01OCT2020)	N/N
	C4591001 1232 12321213	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	01OCT2020	23/C		No	O	P	UNK	N/N
	C4591001 1241 12411010	GENRL	Injection site erythema/ Injection site erythema	1	07AUG2020	1/1	1	Yes		NA	R (07AUG2020)	N/Y
	C4591001 1241 12411011	MUSC	Myalgia/ Myalgia	2	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1241 12411028#	GENRL	Injection site pain/ Injection site pain	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
		GENRL	Fatigue/ Fatigue	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
			Injection site pain/ Injection site pain	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
		GENRL	Pyrexia/ Fever	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
	C4591001 1241 12411034	SURG	Sclerotherapy/ Sclerotherapy	2	23SEP2020	22/1	1	No	O	NA	R (23SEP2020)	N/N
	C4591001 1241 12411127#	GENRL	Injection site pain/ Injection site pain	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
			Pyrexia/ Fever	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
		NERV	Headache/ Headache	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
		GENRL	Injection site pain/ Injection site pain	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N
			Pyrexia/ Fever	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N
		NERV	Headache/ Headache	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N
	C4591001 1241 12411157#	GENRL	Injection site pain/ Injection site pain	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1241 12411171#	MUSC	Myalgia/ Myalgia	3	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N
	C4591001 1241 12411178#	GENRL	Injection site pain/ Injection site pain	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
		GENRL	Fatigue/ Fatigue	4	19FEB2021	2/3	1	Yes		NA	R (21FEB2021)	N/N
			Injection site pain/ Injection site pain	4	19FEB2021	2/3	1	Yes		NA	R (21FEB2021)	N/N
	C4591001 1241 12411205#	GENRL	Injection site pain/ Injection site pain	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N
	C4591001 1241 12411220#	GENRL	Injection site pain/ Injection site pain	3	29JAN2021	2/3	1	Yes		NA	R (31JAN2021)	N/N
			Injection site swelling/ Injection site swelling	3	29JAN2021	2/3	1	Yes		NA	R (31JAN2021)	N/N
		MUSC	Myalgia/ Myalgia	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
	C4591001 1246 12461026	INFEC	Sinusitis/ Sinusitis	2	27OCT2020	9/15	2	No	O	NA/TC	R (10NOV2020)	N/N
	C4591001 1246 12461028#	MUSC	Pain in extremity/ Painful Left arm	3	24FEB2021	1/3	1	Yes		NA/TC	R (26FEB2021)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1246 12461070	INFEC	Urinary tract infection/ Urine tract Infection- pathogen unknown	2	15NOV2020	23/4	2	No	O	NA/TC	R (18NOV2020)	N/N
		PSYCH	Depression/ Worsening of depression	2	25DEC2020	63/22	3	No	O	NA/TC/TCN	R (15JAN2021)	Y/N
	C4591001 1246 12461082#	GENRL	Injection site pain/ Painful Left Arm injection area	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
	C4591001 1246 12461084#	GENRL	Injection site pain/ Painful left arm injection site.	3	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
	C4591001 1246 12461092#	GENRL	Injection site pain/ Painful left arm injection site	3	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
	C4591001 1246 12461094#	GENRL	Injection site pain/ Painful left arm at injection side	3	12FEB2021	1/4	2	Yes		NA/TC	R (15FEB2021)	N/N
	C4591001 1247 12471121	INJ&P	Flail chest/ Flail Chest	2	30OCT2020	10/C	3	No	O	NA/TC/TCN	N	Y/N
			Road traffic accident/ Motorcycle accident	2	30OCT2020	10/1	2	No	O	NA	R (30OCT2020)	N/N
	C4591001 1247 12471185	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/9	1	Yes		NA	R (14OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		NERV	Headache/Headache	1	06OCT2020	1/5	1	Yes		NA	R (10OCT2020)	N/N
		GENRL	Chills/Chills	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
			Injection site pain/Injection site pain	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
		MUSC	Myalgia/Muscle Pain	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
		GENRL	Injection site pain/Injection pain	1	08OCT2020	3/2	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Pyrexia/Fever	2	27OCT2020	1/3	2	Yes		NA	R (29OCT2020)	N/N
	C4591001 1247 12471197	GENRL	Fatigue/Fatigue	1	07OCT2020	2/7	2	Yes		NA	R (13OCT2020)	N/N
		NERV	Headache/Headache	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
	C4591001 1247 12471199	GENRL	Fatigue/Fatigue	1	06OCT2020	1/1	2	Yes		NA	R (06OCT2020)	N/N
			Injection site erythema/Injection site redness	1	06OCT2020	1/2	3	Yes		NA	R (07OCT2020)	N/N
			Injection site pain/Injection site pain	1	06OCT2020	1/2	2	Yes		NA	R (07OCT2020)	N/N
			Injection site swelling/Injection site swelling	1	06OCT2020	1/1	3	Yes		NA	R (06OCT2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1248 12481001	GENRL	Chills/ Chills	2	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
			Pyrexia/ Fever	2	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
	C4591001 1248 12481004#	GENRL	Fatigue/ fatigue	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
			Pain/ body aches	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
			Pyrexia/ mild fever	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
	C4591001 1270 12701152#	GENRL	Chills/ Chills	3	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/N
			Fatigue/ Fatigue	3	03FEB2021	1/7	1	Yes		NA	R (09FEB2021)	N/N
			Injection site pain/ Injection Site Pain	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
		GASTR	Nausea/ Nausea	3	06FEB2021	4/1	1	Yes		NA	R (06FEB2021)	N/N
		GENRL	Injection site pain/ Injection Site Pain	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	C4591001 1270 12701154	PSYCH	Generalised anxiety disorder/ Generalized Anxiety Disorder	2	14JAN2021	39/C	1	No	O	NA/TCN	N	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		MUSC	Back pain/ Chronic Low back pain	2	19JAN2021	44/C	1	No	O	NA/TCN	N	N/N
	C4591001 1270 12701155#	GENRL	Chills/ Chills	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
			Injection site pain/ Injection Site Pain	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N
		MUSC	Myalgia/ Muscle pain, generalized	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	C4591001 1270 12701164#	MUSC	Pain in extremity/ Right antecubital pain	2	02FEB2021	51/1	1	No	O	NA/TCN	R (02FEB2021)	N/N
		NERV	Headache/ Headache	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	C4591001 1270 12701175	GENRL	Injection site pain/ Left Arm Injection Site Pain	1	01DEC2020	1/7	2	Yes		NA	R (07DEC2020)	N/N
	C4591001 1270 12701178	SKIN	Seborrheic dermatitis/ Seborrheic Dermatitis of Scalp	2	10JAN2021	20/C	1	No	O	NA/TC	N	N/N
	C4591001 1270 12701178#	GENRL	Injection site pain/ Injection Site Pain	3	03FEB2021	1/2	1	Yes		NA/TC	R (04FEB2021)	N/N
	C4591001 1270 12701186	SKIN	Rash/ Rash to trunk	2	21JAN2021	31/C	1	No	O	NA	RG	N/N

16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1270 12701190#	GENRL	Injection site pain/ Injection site pain	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
		GENRL	Fatigue/ Fatigue	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	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 (v23.1) coding dictionary applied.

Note: * = Prevaccination AE, # = AE occurring on or after subject unblinding date, † = human immunodeficiency virus (HIV)-positive subject.

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: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_l002_ped

16.2.7.5.1 Listing of Serious Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
12-15	C4591001 1006 10061272	PSYCH	Anxiety/ Worsening of anxiety	1	23DEC2020	8/27	3	No	O	P/TC/TCN	R (18JAN2021)	Y/N
			Depression/ Worsening of Depression	1	23DEC2020	8/27	3	No	O	P/TC/TCN	R (18JAN2021)	Y/N
	C4591001 1007 10071581	INFEC	Appendicitis/ Appendicitis	2	11MAR2021	64/C	3	No	O	NA/TC	RG	Y/N
	C4591001 1007 10071620	NERV	Neuralgia/ generalized Functional neurologic pain	2	21JAN2021	2/C	2	No	O	NA/TC	RG	Y/N
		GASTR	Abdominal pain/ Functional Abdominal Pain	2	28FEB2021	40/C	3	No	O	NA/TC	N	Y/N
			Constipation/ Constipation	2	28FEB2021	40/C	3	No	O	NA/TC	N	Y/N
	C4591001 1039 10391326	PSYCH	Depression/ Depression Exacerbation	1	26JAN2021	16/5	3	No	O	NA/TC/TCN	R (30JAN2021)	Y/N
	C4591001 1123 11231507	PSYCH	Depression/ Worsening of Depression	2	19JAN2021	2/5	2	No	O	NA/TC	R (23JAN2021)	Y/N
	C4591001 1147 11471281	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

16.2.7.5.1 Listing of Serious Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)												
Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-25	C4591001 1270 12701222	PSYCH	Suicidal ideation/ SUICIDAL IDEATION	2	16FEB2021	40/C	3	No	O	NA/TCN	N	Y/N
	C4591001 1003 10031111	MUSC	Psoriatic arthropathy/ psoriatic arthritis	2	26SEP2020	38/C	2	Yes		NA/TC	N	Y/N
	C4591001 1005 10051411	GASTR	Abdominal pain/ ABDOMINAL PAIN	2	29JAN2021	2/4	3	No	O	NA/TC	R (01FEB2021)	Y/N
	C4591001 1129 11291260#	IMMUN	Anaphylactoid reaction/ Anaphylactoid Reaction	3	27JAN2021	3/1	4	Yes		P/TC	R (27JAN2021)	Y/N
	C4591001 1150 11501153#	PSYCH	Depression/ Worsening Depression- no prior hospitalizations for depression	3	02MAR2021	7/C	4	No	O	NA	RG	Y/N
	C4591001 1203 12031026	GASTR	Inguinal hernia/ inguinal hernia left	1	09NOV2020	21/103	2	No	O	NA/TC/TCN	R (19FEB2021)	Y/N
	C4591001 1231 12311281	INFEC	Appendicitis/ acute appendicitis	2	18SEP2020	15/19	3	No	O	NA/TC/TCN	R (06OCT2020)	Y/N
	C4591001 1231 12311387	INFEC	Urinary tract infection/ Complicated Urinary Tract Infection	2	04JAN2021	123/15	3	No	O	NA/TC	R (18JAN2021)	Y/N
	C4591001 1246 12461070	PSYCH	Depression/ Worsening of depression	2	25DEC2020	63/22	3	No	O	NA/TC/TCN	R (15JAN2021)	Y/N

16.2.7.5.1 Listing of Serious Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001124712471121	INJ&P	Flail chest/ Flail Chest	2	30OCT2020	10/C	3	No	O	NA/TC/TCN	N	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 (v23.1) coding dictionary applied.

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

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: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_l002_sae_ped

**16.2.7.6.1 Listing of Adverse Events Leading to Discontinuation –
Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
12-15	C4591001 1006 10061272	PSYCH	Anxiety/ Worsening of anxiety	1	23DEC2020	8/27	3	No	O	P/TC/TCN	R (18JAN2021)	Y/N
			Depression/ Worsening of Depression	1	23DEC2020	8/27	3	No	O	P/TC/TCN	R (18JAN2021)	Y/N
	C4591001 1147 11471327	GENRL	Pyrexia/ Fever (104.7)	1	06JAN2021	2/3	4	Yes		P/TC	R (08JAN2021)	N/N
16-25	C4591001 1096 10961031	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	14AUG2020	1/40		No	O	P	R (22SEP2020)	N/N
	C4591001 1125 11251243	GENRL	Injection site pain/ Grade 3 Pain at Injection site	1	09DEC2020	2/1	3	Yes		P	R (09DEC2020)	N/N
		NERV	Headache/ Grade 3 Headache	1	09DEC2020	2/1	3	Yes		P/TC	R (09DEC2020)	N/N
	C4591001 1129 11291260#	IMMUN	Anaphylactoid reaction/ Anaphylactoid Reaction	3	27JAN2021	3/1	4	Yes		P/TC	R (27JAN2021)	Y/N
	C4591001 1232 12321213	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	01OCT2020	23/C		No	O	P	UNK	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 (v23.1) coding dictionary applied.

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

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.

**16.2.7.6.1 Listing of Adverse Events Leading to Discontinuation –
Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade Rel ^c	Cause of Investigational Vaccine Dose/ Subject	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
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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: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_1002_disc_ped

16.2.7.7.1 Listing of Deaths – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Sex	Date of Death	Age at Death (Years)	Primary Cause of Death	Secondary Cause(s) of Death
No subject meets the reporting criteria.								
Note: MedDRA (v23.1) coding dictionary applied. a. Relative day (Rel Day) = date of death - date of last vaccination + 1. PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adsl Table Generation: 27MAR2021 (06:44) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/cdl_dth_ped								

**16.2.8.1.1 Listing of Subjects With First Severe COVID-19 Occurrence After Dose 1
– Subjects 12 Through 15 Years of Age – Blinded Placebo-Controlled Follow-up Period
– Dose 1 All-Available Efficacy Population – CDC+Protocol**

Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day^a	Start Date	Stop Date	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs, Symptoms, and Events	SARS-CoV-2 NAAT Result (Central Lab/Local Lab^b), Swab Date	Protocol/CDC Defined Symptoms
No subject meets the reporting criteria.								
<p>Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein-binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.</p> <p>Note: HIV-positive subjects are included in this listing but not included in the analyses of the overall study objectives.</p> <p>a. Relative day (Rel Day) = date of first symptom - date of last dose before first symptom + 1.</p> <p>b. SARS-CoV-2 NAAT results from the local lab are based on the Cepheid Xpert[®] Xpress SARS-CoV-2 test, Roche cobas[®] SARS-CoV-2 real-time RT-PCR test (EUA200009/A001), or Abbott RealTime SARS-CoV-2 assay (EUA200023/A001) only.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 27MAR2021 (01:55) Source Data: adsympt Table Generation: 02APR2021 (10:55) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsympt l001_sym_sev_d1_aai_ped</p>								

16.2.8.1.2 Listing of Subjects With First COVID-19 Occurrence After Dose 1 – Subjects 12 Through 15 Years of Age – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day ^a	Start Date of First Symptom	Stop Date of Last Symptom	Baseline Serostatus	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab ^b), Swab Date
C4591001 1006 10061206 (USA/12/M)*	Placebo	Dose 2/10	01JAN2021	03JAN2021	Neg	Neg/Neg/Neg	Fever	Pos/, 01JAN2021
C4591001 1006 10061259 (USA/15/F)	Placebo	Dose 2/7	11JAN2021	24JAN2021	Neg	Neg/Neg/Neg	Fever	Pos/, 18JAN2021
C4591001 1006 10061260 (USA/12/F)*	Placebo	Dose 2/17	21JAN2021	27JAN2021	Neg	Neg/Neg/Neg	New or increased cough Sore throat	Pos/, 21JAN2021
C4591001 1006 10061284 (USA/14/M)	Placebo	Dose 2/8	15JAN2021	16JAN2021	Neg	Neg/Neg/Pos	Diarrhea	Pos/, 18JAN2021
C4591001 1007 10071409 (USA/13/M)	BNT162b2 (30 µg)	Dose 1/10	31OCT2020	04NOV2020	Neg	Neg/Neg/Neg	Fever	Pos/, 02NOV2020
C4591001 1007 10071505 (USA/12/F)	Placebo	Dose 2/2	29DEC2020	08JAN2021	Neg	Neg/Neg/Pos	New loss of taste or smell	Pos/, 03JAN2021
C4591001 1007 10071527 (USA/12/M)	Placebo	Dose 2/10	07JAN2021	10JAN2021	Neg	Neg/Neg/Pos	Sore throat	Pos/Pos, 10JAN2021

16.2.8.1.2 Listing of Subjects With First COVID-19 Occurrence After Dose 1 – Subjects 12 Through 15 Years of Age – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day ^a	Start Date of First Symptom	Stop Date of Last Symptom	Baseline Serostatus	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab ^b), Swab Date
C4591001 1007 10071559 (USA/14/F)*	Placebo	Dose 2/11	14JAN2021	26JAN2021	Neg	Neg/Neg/Neg	Fever	Pos/, 15JAN2021
C4591001 1007 10071603 (USA/13/M)*	Placebo	Dose 2/35	22FEB2021	28FEB2021	Neg	Neg/Neg/Neg	Sore throat Fever	Pos/, 23FEB2021
C4591001 1007 10071622 (USA/15/M)	BNT162b2 (30 µg)	Dose 1/2	31DEC2020	15FEB2021	Neg	Neg/Neg/Neg	New loss of taste or smell Sore throat New or increased muscle pain	Pos/, 04JAN2021
C4591001 1007 10071642 (USA/15/M)	BNT162b2 (30 µg)	Dose 1/7	10JAN2021	20JAN2021	Neg	Neg/Neg/Pos	New loss of taste or smell New or increased cough	Pos/, 12JAN2021
C4591001 1008 10081871 (USA/14/F)	Placebo	Dose 1/14	12JAN2021	19JAN2021	Neg	Neg/Neg/Neg	Sore throat New or increased cough	Pos/, 18JAN2021
C4591001 1008 10081884 (USA/15/F)	Placebo	Dose 1/19	18JAN2021	26JAN2021	Neg	Neg/Neg/Pos	Sore throat Sore throat	Pos/, 20JAN2021

16.2.8.1.2 Listing of Subjects With First COVID-19 Occurrence After Dose 1 – Subjects 12 Through 15 Years of Age – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day ^a	Start Date of First Symptom	Stop Date of Last Symptom	Baseline Serostatus	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab ^b), Swab Date
C4591001 1009 10091208 (USA/15/M)*	Placebo	Dose 2/66	10JAN2021	14JAN2021	Neg	Neg/Neg/Neg	New or increased cough New or increased shortness of breath New or increased muscle pain Sore throat	Pos/, 10JAN2021
C4591001 1009 10091282 (USA/14/M)*	Placebo	Dose 2/42	01FEB2021	02FEB2021	Neg	Neg/Neg/Neg	Chills New or increased muscle pain New loss of taste or smell Sore throat	Pos/, 02FEB2021
C4591001 1009 10091338 (USA/15/F)	Placebo	Dose 1/19	01JAN2021	24FEB2021	Neg	Neg/Neg/Pos	Fever New or increased cough New or increased muscle pain Sore throat	Pos/, 02JAN2021

16.2.8.1.2 Listing of Subjects With First COVID-19 Occurrence After Dose 1 – Subjects 12 Through 15 Years of Age – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day ^a	Start Date of First Symptom	Stop Date of Last Symptom	Baseline Serostatus	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab ^b), Swab Date
C4591001 1009 10091366 (USA/14/F)	Placebo	Dose 1/9	25DEC2020	01JAN2021	Neg	Neg/Neg/Pos	Fever	Pos/, 28DEC2020
C4591001 1009 10091412 (USA/15/M)*	Placebo	Dose 2/29	01MAR2021		Neg	Neg/Neg/Neg	Chills New or increased muscle pain Sore throat	Pos/, 01MAR2021
C4591001 1016 10161316 (USA/15/M)	Placebo	Dose 1/17	01NOV2020	11NOV2020	Neg	Neg/Neg/Pos	Sore throat New or increased cough	Pos/, 02NOV2020
C4591001 1016 10161319 (USA/12/F)	Placebo	Dose 2/6	09NOV2020	20NOV2020	Neg	Neg/Neg/Neg	Chills New or increased muscle pain New loss of taste or smell Sore throat Diarrhea	Pos/, 10NOV2020

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16.2.8.1.2 Listing of Subjects With First COVID-19 Occurrence After Dose 1 – Subjects 12 Through 15 Years of Age – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day ^a	Start Date of First Symptom	Stop Date of Last Symptom	Baseline Serostatus	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab ^b), Swab Date
C4591001 1016 10161379 (USA/13/M)	Placebo	Dose 1/13	19JAN2021	02FEB2021	Neg	Neg/Neg/Neg	New or increased cough Chills New loss of taste or smell Sore throat	Pos/ (R1 Pos), 19JAN2021 (29JAN2021)
C4591001 1039 10391268 (USA/13/F)*	Placebo	Dose 2/33	29JAN2021	03MAR2021	Neg	Neg/Neg/Neg	New loss of taste or smell Sore throat Fever	Pos/, 29JAN2021
C4591001 1044 10441264 (USA/14/F)	Placebo	Dose 2/6	02JAN2021		Neg	Neg/Neg/Neg	New or increased cough New or increased shortness of breath Chills New or increased muscle pain New or increased cough	Pos/, 04JAN2021

16.2.8.1.2 Listing of Subjects With First COVID-19 Occurrence After Dose 1 – Subjects 12 Through 15 Years of Age – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day ^a	Start Date of First Symptom	Stop Date of Last Symptom	Baseline Serostatus	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab ^b), Swab Date
C4591001 1044 10441374 (USA/15/M)*	Placebo	Dose 2/13	14FEB2021	17FEB2021	Neg	Neg/Neg/Neg	Sore throat Chills	Pos/, 16FEB2021
C4591001 1057 10571428 (USA/14/M)	Placebo	Dose 1/5	28DEC2020	02JAN2021	Neg	Neg/Neg/Pos	New loss of taste or smell Vomiting Fever	Pos/, 29DEC2020
C4591001 1091 10911404 (USA/13/F)*	Placebo	Dose 2/27	23JAN2021		Neg	Neg/Neg/Neg	Chills Sore throat New or increased shortness of breath	Pos/, 25JAN2021
C4591001 1091 10911407 (USA/12/M)	Placebo	Dose 2/6	02JAN2021	16JAN2021	Neg	Neg/Neg/Neg	Chills New or increased muscle pain New loss of taste or smell Sore throat Diarrhea New or increased cough	Pos/, 06JAN2021

16.2.8.1.2 Listing of Subjects With First COVID-19 Occurrence After Dose 1 – Subjects 12 Through 15 Years of Age – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day ^a	Start Date of First Symptom	Stop Date of Last Symptom	Baseline Serostatus	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab ^b), Swab Date
C4591001 1123 11231501 (USA/12/F)	Placebo	Dose 1/18	14JAN2021	02FEB2021	Neg	Neg/Neg/Neg	New or increased muscle pain Diarrhea Fever	Pos/, 19JAN2021
C4591001 1126 11261287 (USA/15/M)	Placebo	Dose 1/15	30DEC2020	11JAN2021	Neg	Neg/Neg/Pos	New or increased cough New or increased muscle pain New loss of taste or smell Sore throat Fever	Pos/, 04JAN2021
C4591001 1142 11421388 (USA/15/M)*	Placebo	Dose 2/25	19FEB2021		Neg	Neg/Neg/Neg	Sore throat	Pos/, 19FEB2021
C4591001 1147 11471280 (USA/12/M)	Placebo	Dose 1/6	09JAN2021	12JAN2021	Neg	Neg/Neg/Unk	Fever	Pos/, 10JAN2021
C4591001 1150 11501204 (USA/14/M)*	Placebo	Dose 2/32	04FEB2021		Neg	Neg/Neg/Neg	Chills New or increased cough	Pos/, 05FEB2021

16.2.8.1.2 Listing of Subjects With First COVID-19 Occurrence After Dose 1 – Subjects 12 Through 15 Years of Age – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day ^a	Start Date of First Symptom	Stop Date of Last Symptom	Baseline Serostatus	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab ^b), Swab Date
C4591001 1150 11501291 (USA/15/M)	Placebo	Dose 1/2	12JAN2021	26JAN2021	Neg	Neg/Neg/Neg	Sore throat New or increased cough	Pos/, 13JAN2021
C4591001 1152 11521666 (USA/15/F)*	Placebo	Dose 2/17	15JAN2021	23JAN2021	Neg	Neg/Neg/Neg	Sore throat New or increased cough	Pos/, 21JAN2021
C4591001 1156 11561260 (USA/15/F)*	Placebo	Dose 2/82	01FEB2021	05FEB2021	Neg	Neg/Neg/Neg	New or increased muscle pain New loss of taste or smell	Pos/, 01FEB2021
C4591001 1156 11561263 (USA/15/M)*	Placebo	Dose 2/41	20DEC2020	25DEC2020	Neg	Neg/Neg/Neg	New or increased cough	Pos/, 22DEC2020
C4591001 1235 12351243 (USA/15/M)*	Placebo	Dose 2/42	09FEB2021	11FEB2021	Neg	Neg/Neg/Neg	New or increased cough	Pos/, 11FEB2021
C4591001 1270 12701237 (USA/13/F)	Placebo	Dose 1/13	19JAN2021	20JAN2021	Pos	Neg/Pos/Pos	Sore throat Diarrhea New or increased shortness of breath	Pos/, 21JAN2021

16.2.8.1.2 Listing of Subjects With First COVID-19 Occurrence After Dose 1 – Subjects 12 Through 15 Years of Age – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

Subject (Country/Age in Years/Sex)	Vaccine Group (as Randomized)	Dose/Rel Day ^a	Start Date of First Symptom	Stop Date of Last Symptom	Baseline Serostatus	Visit 1 N-Binding Assay/ Visit 1 NAAT/ Visit 2 NAAT	Signs and Symptoms	SARS-CoV-2 NAAT Result (Central Lab/Local Lab ^b), Swab Date
<p>Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein-binding; Neg = negative; Pos = positive; R1 = repeat central swab 1; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; Unk = unknown.</p> <p>Note: * indicates subject in the evaluable efficacy (7 days) population with first COVID-19 occurrence from 7 days after Dose 2 and without evidence of infection prior to 7 days after Dose 2.</p> <p>Note: HIV-positive subjects are included in this listing but not included in the analyses of the overall study objectives.</p> <p>a. Relative day (Rel Day) = date of first symptom - date of last dose before first symptom + 1.</p> <p>b. SARS-CoV-2 NAAT results from the local lab are based on the Cepheid Xpert[®] Xpress SARS-CoV-2 test, Roche cobas[®] SARS-CoV-2 real-time RT-PCR test (EUA200009/A001), or Abbott RealTime SARS-CoV-2 assay (EUA200023/A001) only.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 27MAR2021 (01:55) Source Data: adsympt Table Generation: 04APR2021 (00:39) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsympt_l001_sympt_d1_ped_aai</p>								