E-Diary Transmission – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years n[a] (%)	16-25 Years n[a] (%)	12-15 Years n[a] (%)	16-25 Years n[a] (%)
Vaccinated at Dose 1[b]	1131	537	1129	561
E-diary				
Not transmitted[c]	4 (0.4)	3 (0.6)	2 (0.2)	8 (1.4)
Transmitted[d]				
Day 1	1081 (95.6)	509 (94.8)	1066 (94.4)	514 (91.6)
Day 2	1090 (96.4)	512 (95.3)	1073 (95.0)	519 (92.5)
Day 3	1049 (92.7)	488 (90.9)	1056 (93.5)	515 (91.8)
Day 4	1025 (90.6)	480 (89.4)	1011 (89.5)	504 (89.8)
Day 5	1012 (89.5)	473 (88.1)	1003 (88.8)	492 (87.7)
Day 6	991 (87.6)	476 (88.6)	1002 (88.8)	484 (86.3)
Day 7	1006 (88.9)	478 (89.0)	990 (87.7)	476 (84.8)
All 7 days[e]	719 (63.6)	349 (65.0)	697 (61.7)	344 (61.3)
Vaccinated at Dose 2[b]	1124	525	1117	535
E-diary				
Not transmitted[c]	23 (2.0)	31 (5.9)	38 (3.4)	38 (7.1)
Transmitted[d]				
Day 1	858 (76.3)	381 (72.6)	786 (70.4)	350 (65.4)
Day 2	991 (88.2)	446 (85.0)	881 (78.9)	408 (76.3)
Day 3	963 (85.7)	424 (80.8)	905 (81.0)	428 (80.0)
Day 4	914 (81.3)	420 (80.0)	907 (81.2)	431 (80.6)

E-Diary Transmission – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years n[a] (%)	16-25 Years n[a] (%)	12-15 Years n[a] (%)	16-25 Years n[a] (%)
Day 5	917 (81.6)	423 (80.6)	909 (81.4)	433 (80.9)
Day 6	931 (82.8)	414 (78.9)	923 (82.6)	425 (79.4)
Day 7	925 (82.3)	412 (78.5)	912 (81.6)	427 (79.8)
All 7 days[e]	465 (41.4)	220 (41.9)	415 (37.2)	201 (37.6)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. If no data for temperature, local reactions, fever/pain medication, or systemic events are reported for the entire electronic diary (e-diary) or AE collection page for Day 1 through Day 7 after vaccination, the e-diary is considered not transmitted.
d. If any data for temperature, local reactions, fever/pain medication, or systemic events are reported for the specified day or set of days (ie, "all 7 days"), the e-diary is considered transmitted.
e. "All 7 days" includes Day 1 through Day 7 after vaccination. Day 1 is the day of vaccination.
PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (21:11) Source Data: adfacevd Table Generation: 25JAN2022 (02:18)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_Peds_EDIARY/adce_s200_trns_ped_saf

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]												
	Any	1127	65 (5.8)	(4.5, 7.3)	531	34 (6.4)	(4.5, 8.8)	1127	12 (1.1)	(0.6, 1.9)	553	7 (1.3)	(0.5, 2.6)
	Mild	1127	44 (3.9)	(2.9, 5.2)	531	25 (4.7)	(3.1, 6.9)	1127	11 (1.0)	(0.5, 1.7)	553	6 (1.1)	(0.4, 2.3)
	Moderate	1127	20 (1.8)	(1.1, 2.7)	531	7 (1.3)	(0.5, 2.7)	1127	1 (0.1)	(0.0, 0.5)	553	1 (0.2)	(0.0, 1.0)
	Severe	1127	1 (0.1)	(0.0, 0.5)	531	2 (0.4)	(0.0, 1.4)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Swelling[d]												
	Any	1127	78 (6.9)	(5.5, 8.6)	531	44 (8.3)	(6.1, 11.0)	1127	11 (1.0)	(0.5, 1.7)	553	6 (1.1)	(0.4, 2.3)
	Mild	1127	55 (4.9)	(3.7, 6.3)	531	31 (5.8)	(4.0, 8.2)	1127	9 (0.8)	(0.4, 1.5)	553	3 (0.5)	(0.1, 1.6)
	Moderate	1127	23 (2.0)	(1.3, 3.0)	531	12 (2.3)	(1.2, 3.9)	1127	2 (0.2)	(0.0, 0.6)	553	3 (0.5)	(0.1, 1.6)
	Severe	1127	0	(0.0, 0.3)	531	1 (0.2)	(0.0, 1.0)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Pain at the injection site[e]												
	Any	1127	973 (86.3)	(84.2, 88.3)	532	444 (83.5)	(80.0, 86.5)	1127	267 (23.7)	(21.2, 26.3)	553	88 (15.9)	(13.0, 19.2)
	Mild	1127	469 (41.6)	(38.7, 44.6)	532	203 (38.2)	(34.0, 42.4)	1127	231 (20.5)	(18.2, 23.0)	553	81 (14.6)	(11.8, 17.9)
	Moderate	1127	493 (43.7)	(40.8, 46.7)	532	229 (43.0)	(38.8, 47.4)	1127	36 (3.2)	(2.2, 4.4)	553	7 (1.3)	(0.5, 2.6)
	Severe	1127	11 (1.0)	(0.5, 1.7)	532	12 (2.3)	(1.2, 3.9)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	532	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Any local reaction[f]	1127	978 (86.8)	(84.7, 88.7)	532	446 (83.8)	(80.4, 86.9)	1127	275 (24.4)	(21.9, 27.0)	553	93 (16.8)	(13.8, 20.2)

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
2	Redness[d]												
	Any	1097	55 (5.0)	(3.8, 6.5)	488	28 (5.7)	(3.8, 8.2)	1078	10 (0.9)	(0.4, 1.7)	496	1 (0.2)	(0.0, 1.1)
	Mild	1097	29 (2.6)	(1.8, 3.8)	488	18 (3.7)	(2.2, 5.8)	1078	8 (0.7)	(0.3, 1.5)	496	1 (0.2)	(0.0, 1.1)
	Moderate	1097	26 (2.4)	(1.6, 3.5)	488	9 (1.8)	(0.8, 3.5)	1078	2 (0.2)	(0.0, 0.7)	496	0	(0.0, 0.7)
	Severe	1097	0	(0.0, 0.3)	488	1 (0.2)	(0.0, 1.1)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Swelling[d]												
	Any	1098	55 (5.0)	(3.8, 6.5)	489	34 (7.0)	(4.9, 9.6)	1078	6 (0.6)	(0.2, 1.2)	496	1 (0.2)	(0.0, 1.1)
	Mild	1098	36 (3.3)	(2.3, 4.5)	489	24 (4.9)	(3.2, 7.2)	1078	4 (0.4)	(0.1, 0.9)	496	1 (0.2)	(0.0, 1.1)
	Moderate	1098	19 (1.7)	(1.0, 2.7)	489	10 (2.0)	(1.0, 3.7)	1078	2 (0.2)	(0.0, 0.7)	496	0	(0.0, 0.7)
	Severe	1098	0	(0.0, 0.3)	489	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1098	0	(0.0, 0.3)	489	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Pain at the injection site[e]												
	Any	1101	870 (79.0)	(76.5, 81.4)	490	380 (77.6)	(73.6, 81.2)	1079	194 (18.0)	(15.7, 20.4)	496	61 (12.3)	(9.5, 15.5)
	Mild	1101	467 (42.4)	(39.5, 45.4)	490	204 (41.6)	(37.2, 46.1)	1079	165 (15.3)	(13.2, 17.6)	496	54 (10.9)	(8.3, 14.0)
	Moderate	1101	396 (36.0)	(33.1, 38.9)	490	169 (34.5)	(30.3, 38.9)	1079	29 (2.7)	(1.8, 3.8)	496	7 (1.4)	(0.6, 2.9)
	Severe	1101	7 (0.6)	(0.3, 1.3)	490	7 (1.4)	(0.6, 2.9)	1079	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1101	0	(0.0, 0.3)	490	0	(0.0, 0.8)	1079	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Any local reaction[f]	1101	876 (79.6)	(77.1, 81.9)	490	383 (78.2)	(74.2, 81.7)	1079	199 (18.4)	(16.2, 20.9)	496	63 (12.7)	(9.9, 16.0)

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Any dose	Redness[d]												
	Any	1131	97 (8.6)	(7.0, 10.4)	535	55 (10.3)	(7.8, 13.2)	1129	18 (1.6)	(0.9, 2.5)	555	7 (1.3)	(0.5, 2.6)
	Mild	1131	55 (4.9)	(3.7, 6.3)	535	37 (6.9)	(4.9, 9.4)	1129	15 (1.3)	(0.7, 2.2)	555	6 (1.1)	(0.4, 2.3)
	Moderate	1131	41 (3.6)	(2.6, 4.9)	535	15 (2.8)	(1.6, 4.6)	1129	3 (0.3)	(0.1, 0.8)	555	1 (0.2)	(0.0, 1.0)
	Severe	1131	1 (0.1)	(0.0, 0.5)	535	3 (0.6)	(0.1, 1.6)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Swelling[d]												
	Any	1131	104 (9.2)	(7.6, 11.0)	535	62 (11.6)	(9.0, 14.6)	1129	13 (1.2)	(0.6, 2.0)	555	7 (1.3)	(0.5, 2.6)
	Mild	1131	68 (6.0)	(4.7, 7.6)	535	45 (8.4)	(6.2, 11.1)	1129	10 (0.9)	(0.4, 1.6)	555	4 (0.7)	(0.2, 1.8)
	Moderate	1131	36 (3.2)	(2.2, 4.4)	535	16 (3.0)	(1.7, 4.8)	1129	3 (0.3)	(0.1, 0.8)	555	3 (0.5)	(0.1, 1.6)
	Severe	1131	0	(0.0, 0.3)	535	1 (0.2)	(0.0, 1.0)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Pain at the injection site[e]												
	Any	1131	1024 (90.5)	(88.7, 92.2)	535	468 (87.5)	(84.4, 90.2)	1129	344 (30.5)	(27.8, 33.2)	555	122 (22.0)	(18.6, 25.7)
	Mild	1131	393 (34.7)	(32.0, 37.6)	535	167 (31.2)	(27.3, 35.3)	1129	286 (25.3)	(22.8, 28.0)	555	109 (19.6)	(16.4, 23.2)
	Moderate	1131	614 (54.3)	(51.3, 57.2)	535	283 (52.9)	(48.6, 57.2)	1129	58 (5.1)	(3.9, 6.6)	555	13 (2.3)	(1.3, 4.0)
	Severe	1131	17 (1.5)	(0.9, 2.4)	535	18 (3.4)	(2.0, 5.3)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Any local reaction[f]	1131	1029 (91.0)	(89.2, 92.6)	535	471 (88.0)	(85.0, 90.7)	1129	352 (31.2)	(28.5, 34.0)	555	127 (22.9)	(19.5, 26.6)

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (21:11) Source Data: adfacevd Table Generation: 21JAN2022 (09:17)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 sBLA Peds EDIARY/adce s010 lr sev ped saf

**Duration (Days) From First to Last Day of Local Reactions –
Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Local Reaction	12-15 Years	16-25 Years	12-15 Years	16-25 Years
1	Redness				
	n[a]	65	34	12	7
	Mean (SD)	2.4 (2.26)	1.8 (0.97)	1.3 (0.62)	1.3 (0.49)
	Median	2.0	2.0	1.0	1.0
	Min, max	(1, 16)	(1, 5)	(1, 3)	(1, 2)
	Swelling				
	n[a]	78	44	11	6
	Mean (SD)	1.9 (1.10)	2.0 (1.50)	1.7 (1.35)	1.3 (0.82)
	Median	2.0	1.0	1.0	1.0
	Min, max	(1, 5)	(1, 7)	(1, 5)	(1, 3)
	Pain at the injection site				
	n[a]	973	444	267	88
	Mean (SD)	2.4 (1.35)	2.3 (1.37)	2.0 (1.73)	1.5 (1.27)
	Median	2.0	2.0	1.0	1.0
	Min, max	(1, 10)	(1, 9)	(1, 10)	(1, 11)
2	Redness				
	n[a]	55	28	10	1
	Mean (SD)	1.8 (0.88)	1.9 (1.43)	1.7 (1.16)	1.0 (NE)
	Median	2.0	1.5	1.0	1.0
	Min, max	(1, 5)	(1, 8)	(1, 4)	(1, 1)
	Unknown[b]	1	0	0	0

Duration (Days) From First to Last Day of Local Reactions – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	**Local Reaction**	**12-15 Years**	**16-25 Years**	**12-15 Years**	**16-25 Years**
	Swelling				
	n[a]	55	34	6	1
	Mean (SD)	1.7 (0.93)	2.3 (1.69)	1.5 (0.55)	3.0 (NE)
	Median	1.0	2.0	1.5	3.0
	Min, max	(1, 5)	(1, 7)	(1, 2)	(3, 3)
	Pain at the injection site				
	n[a]	870	380	194	61
	Mean (SD)	2.5 (1.38)	2.8 (4.30)	1.8 (1.43)	2.2 (4.42)
	Median	2.0	2.0	1.0	1.0
	Min, max	(1, 11)	(1, 70)	(1, 8)	(1, 35)
	Unknown[b]	3	3	0	0

Abbreviation: NE = not estimable.
Note: Duration was calculated in days as the difference from the start of the first reported reaction to the resolution of the last reported reaction, inclusive. For symptoms that are ongoing at the time of the next dose, stop date is computed as the next dose date.
Note: Reactions were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. The resolution date for reactions lasting longer than 7 days was recorded on the subject's case report form.
a. n = Number of subjects reporting the specified reaction on any of the 7 days, including subjects with reactions of unknown duration.
b. Includes those reactions where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (21:06) Source Data: adcevd Table Generation: 21JAN2022 (09:17)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 sBLA Peds EDIARY/adce s030 lr dur ped saf

Onset Days for Local Reactions – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	**Local Reaction**	**12-15 Years**	**16-25 Years**	**12-15 Years**	**16-25 Years**
1	Redness				
	n[a]	65	34	12	7
	Mean (SD)	2.4 (0.82)	2.4 (1.05)	1.8 (1.11)	1.6 (1.13)
	Median	2.0	2.0	1.5	1.0
	Min, max	(1, 4)	(1, 5)	(1, 4)	(1, 4)
	Swelling				
	n[a]	78	44	11	6
	Mean (SD)	1.9 (0.85)	2.2 (1.02)	1.6 (1.21)	1.3 (0.82)
	Median	2.0	2.0	1.0	1.0
	Min, max	(1, 5)	(1, 5)	(1, 4)	(1, 3)
	Pain at the injection site				
	n[a]	973	444	267	88
	Mean (SD)	1.4 (0.55)	1.4 (0.50)	1.3 (0.83)	1.5 (1.05)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 7)	(1, 4)	(1, 7)	(1, 7)
	Any local reaction[b]				
	n[a]	978	446	275	93
	Mean (SD)	1.4 (0.56)	1.4 (0.51)	1.4 (0.87)	1.5 (1.05)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 7)	(1, 4)	(1, 7)	(1, 7)
2	Redness				

Onset Days for Local Reactions – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	**Local Reaction**	**12-15 Years**	**16-25 Years**	**12-15 Years**	**16-25 Years**
	n[a]	55	28	10	1
	Mean (SD)	2.5 (0.84)	2.6 (0.79)	1.2 (0.42)	1.0 (NE)
	Median	2.0	3.0	1.0	1.0
	Min, max	(1, 5)	(1, 4)	(1, 2)	(1, 1)
	Swelling				
	n[a]	55	34	6	1
	Mean (SD)	2.0 (0.96)	2.0 (0.97)	2.8 (2.86)	3.0 (NE)
	Median	2.0	2.0	1.0	3.0
	Min, max	(1, 4)	(1, 4)	(1, 7)	(3, 3)
	Pain at the injection site				
	n[a]	870	380	194	61
	Mean (SD)	1.4 (0.61)	1.4 (0.62)	1.5 (1.13)	1.6 (1.05)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 6)	(1, 6)	(1, 7)	(1, 6)
	Any local reaction[b]				
	n[a]	876	383	199	63
	Mean (SD)	1.4 (0.62)	1.4 (0.63)	1.5 (1.08)	1.6 (1.05)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 6)	(1, 6)	(1, 7)	(1, 6)

Abbreviation: NE = not estimable.
Note: Day of onset is the first day the specified reaction was reported.
a. n = Number of subjects reporting the specified reaction, with each subject counted only once per reaction.
b. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.

Onset Days for Local Reactions – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Local Reaction	12-15 Years	16-25 Years	12-15 Years	16-25 Years

PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (21:11) Source Data: adfacevd Table Generation: 21JAN2022 (09:17)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_Peds_EDIARY/adce_s050_lr_onset_ped_saf

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever												
	Any	1127	114 (10.1)	(8.4, 12.0)	531	39 (7.3)	(5.3, 9.9)	1127	12 (1.1)	(0.6, 1.9)	553	8 (1.4)	(0.6, 2.8)
	≥38.0°C to 38.4°C	1127	74 (6.6)	(5.2, 8.2)	531	24 (4.5)	(2.9, 6.7)	1127	8 (0.7)	(0.3, 1.4)	553	5 (0.9)	(0.3, 2.1)
	>38.4°C to 38.9°C	1127	29 (2.6)	(1.7, 3.7)	531	12 (2.3)	(1.2, 3.9)	1127	2 (0.2)	(0.0, 0.6)	553	2 (0.4)	(0.0, 1.3)
	>38.9°C to 40.0°C	1127	10 (0.9)	(0.4, 1.6)	531	3 (0.6)	(0.1, 1.6)	1127	2 (0.2)	(0.0, 0.6)	553	1 (0.2)	(0.0, 1.0)
	>40.0°C	1127	1 (0.1)	(0.0, 0.5)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Unknown[d]	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Fatigue[e]												
	Any	1127	678 (60.2)	(57.2, 63.0)	532	319 (60.0)	(55.7, 64.2)	1127	457 (40.6)	(37.7, 43.5)	553	213 (38.5)	(34.4, 42.7)
	Mild	1127	279 (24.8)	(22.3, 27.4)	532	135 (25.4)	(21.7, 29.3)	1127	250 (22.2)	(19.8, 24.7)	553	118 (21.3)	(18.0, 25.0)
	Moderate	1127	384 (34.1)	(31.3, 36.9)	532	173 (32.5)	(28.6, 36.7)	1127	199 (17.7)	(15.5, 20.0)	553	89 (16.1)	(13.1, 19.4)
	Severe	1127	15 (1.3)	(0.7, 2.2)	532	11 (2.1)	(1.0, 3.7)	1127	8 (0.7)	(0.3, 1.4)	553	6 (1.1)	(0.4, 2.3)
	Grade 4	1127	0	(0.0, 0.3)	532	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Headache[e]												
	Any	1127	624 (55.4)	(52.4, 58.3)	533	288 (54.0)	(49.7, 58.3)	1127	396 (35.1)	(32.3, 38.0)	553	205 (37.1)	(33.0, 41.2)
	Mild	1127	362 (32.1)	(29.4, 34.9)	533	153 (28.7)	(24.9, 32.8)	1127	256 (22.7)	(20.3, 25.3)	553	138 (25.0)	(21.4, 28.8)
	Moderate	1127	251 (22.3)	(19.9, 24.8)	533	124 (23.3)	(19.7, 27.1)	1127	131 (11.6)	(9.8, 13.6)	553	63 (11.4)	(8.9, 14.3)
	Severe	1127	11 (1.0)	(0.5, 1.7)	533	11 (2.1)	(1.0, 3.7)	1127	9 (0.8)	(0.4, 1.5)	553	4 (0.7)	(0.2, 1.8)
	Grade 4	1127	0	(0.0, 0.3)	533	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Chills[e]												

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	1127	312 (27.7)	(25.1, 30.4)	532	134 (25.2)	(21.6, 29.1)	1127	109 (9.7)	(8.0, 11.5)	553	47 (8.5)	(6.3, 11.1)
	Mild	1127	195 (17.3)	(15.1, 19.6)	532	91 (17.1)	(14.0, 20.6)	1127	82 (7.3)	(5.8, 9.0)	553	31 (5.6)	(3.8, 7.9)
	Moderate	1127	112 (9.9)	(8.3, 11.8)	532	38 (7.1)	(5.1, 9.7)	1127	25 (2.2)	(1.4, 3.3)	553	15 (2.7)	(1.5, 4.4)
	Severe	1127	5 (0.4)	(0.1, 1.0)	532	5 (0.9)	(0.3, 2.2)	1127	2 (0.2)	(0.0, 0.6)	553	1 (0.2)	(0.0, 1.0)
	Grade 4	1127	0	(0.0, 0.3)	532	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Vomiting[f]												
	Any	1127	31 (2.8)	(1.9, 3.9)	531	9 (1.7)	(0.8, 3.2)	1127	10 (0.9)	(0.4, 1.6)	553	9 (1.6)	(0.7, 3.1)
	Mild	1127	30 (2.7)	(1.8, 3.8)	531	9 (1.7)	(0.8, 3.2)	1127	8 (0.7)	(0.3, 1.4)	553	8 (1.4)	(0.6, 2.8)
	Moderate	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	2 (0.2)	(0.0, 0.6)	553	0	(0.0, 0.7)
	Severe	1127	1 (0.1)	(0.0, 0.5)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	1 (0.2)	(0.0, 1.0)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Diarrhea[g]												
	Any	1127	90 (8.0)	(6.5, 9.7)	531	57 (10.7)	(8.2, 13.7)	1127	83 (7.4)	(5.9, 9.0)	553	62 (11.2)	(8.7, 14.1)
	Mild	1127	77 (6.8)	(5.4, 8.5)	531	50 (9.4)	(7.1, 12.2)	1127	73 (6.5)	(5.1, 8.1)	553	49 (8.9)	(6.6, 11.5)
	Moderate	1127	13 (1.2)	(0.6, 2.0)	531	7 (1.3)	(0.5, 2.7)	1127	10 (0.9)	(0.4, 1.6)	553	13 (2.4)	(1.3, 4.0)
	Severe	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	New or worsened muscle pain[e]												
	Any	1127	272 (24.1)	(21.7, 26.7)	532	144 (27.1)	(23.3, 31.1)	1127	148 (13.1)	(11.2, 15.2)	553	78 (14.1)	(11.3, 17.3)
	Mild	1127	125 (11.1)	(9.3, 13.1)	532	67 (12.6)	(9.9, 15.7)	1127	88 (7.8)	(6.3, 9.5)	553	51 (9.2)	(6.9, 11.9)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	1127	145 (12.9)	(11.0, 15.0)	532	72 (13.5)	(10.7, 16.7)	1127	60 (5.3)	(4.1, 6.8)	553	27 (4.9)	(3.2, 7.0)
	Severe	1127	2 (0.2)	(0.0, 0.6)	532	5 (0.9)	(0.3, 2.2)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	532	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	New or worsened joint pain[e]												
	Any	1127	109 (9.7)	(8.0, 11.5)	531	70 (13.2)	(10.4, 16.4)	1127	77 (6.8)	(5.4, 8.5)	553	28 (5.1)	(3.4, 7.2)
	Mild	1127	66 (5.9)	(4.6, 7.4)	531	38 (7.2)	(5.1, 9.7)	1127	50 (4.4)	(3.3, 5.8)	553	17 (3.1)	(1.8, 4.9)
	Moderate	1127	42 (3.7)	(2.7, 5.0)	531	29 (5.5)	(3.7, 7.7)	1127	27 (2.4)	(1.6, 3.5)	553	11 (2.0)	(1.0, 3.5)
	Severe	1127	1 (0.1)	(0.0, 0.5)	531	3 (0.6)	(0.1, 1.6)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Any systemic event[h]	1127	878 (77.9)	(75.4, 80.3)	533	405 (76.0)	(72.1, 79.6)	1127	637 (56.5)	(53.6, 59.4)	553	311 (56.2)	(52.0, 60.4)
	Use of antipyretic or pain medication[i]	1127	413 (36.6)	(33.8, 39.5)	531	167 (31.5)	(27.5, 35.6)	1127	111 (9.8)	(8.2, 11.7)	553	62 (11.2)	(8.7, 14.1)
2	Fever												
	Any	1098	217 (19.8)	(17.4, 22.2)	489	88 (18.0)	(14.7, 21.7)	1078	7 (0.6)	(0.3, 1.3)	496	2 (0.4)	(0.0, 1.4)
	≥38.0°C to 38.4°C	1098	107 (9.7)	(8.1, 11.7)	489	45 (9.2)	(6.8, 12.1)	1078	5 (0.5)	(0.2, 1.1)	496	1 (0.2)	(0.0, 1.1)
	>38.4°C to 38.9°C	1098	83 (7.6)	(6.1, 9.3)	489	32 (6.5)	(4.5, 9.1)	1078	1 (0.1)	(0.0, 0.5)	496	0	(0.0, 0.7)
	>38.9°C to 40.0°C	1098	25 (2.3)	(1.5, 3.3)	489	7 (1.4)	(0.6, 2.9)	1078	1 (0.1)	(0.0, 0.5)	496	1 (0.2)	(0.0, 1.1)
	>40.0°C	1098	0	(0.0, 0.3)	489	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Unknown[d]	1098	2 (0.2)	(0.0, 0.7)	489	4 (0.8)	(0.2, 2.1)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Fatigue[e]												

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any	1101	732 (66.5)	(63.6, 69.3)	490	323 (65.9)	(61.5, 70.1)	1079	265 (24.6)	(22.0, 27.2)	496	116 (23.4)	(19.7, 27.4)
	Mild	1101	234 (21.3)	(18.9, 23.8)	490	100 (20.4)	(16.9, 24.3)	1079	134 (12.4)	(10.5, 14.5)	496	52 (10.5)	(7.9, 13.5)
	Moderate	1101	472 (42.9)	(39.9, 45.9)	490	200 (40.8)	(36.4, 45.3)	1079	127 (11.8)	(9.9, 13.8)	496	62 (12.5)	(9.7, 15.7)
	Severe	1101	26 (2.4)	(1.5, 3.4)	490	23 (4.7)	(3.0, 7.0)	1079	4 (0.4)	(0.1, 0.9)	496	2 (0.4)	(0.0, 1.4)
	Grade 4	1101	0	(0.0, 0.3)	490	0	(0.0, 0.8)	1079	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Headache[e]												
	Any	1099	710 (64.6)	(61.7, 67.4)	490	300 (61.2)	(56.8, 65.6)	1078	263 (24.4)	(21.9, 27.1)	496	118 (23.8)	(20.1, 27.8)
	Mild	1099	302 (27.5)	(24.9, 30.2)	490	121 (24.7)	(20.9, 28.8)	1078	169 (15.7)	(13.6, 18.0)	496	67 (13.5)	(10.6, 16.8)
	Moderate	1099	386 (35.1)	(32.3, 38.0)	490	158 (32.2)	(28.1, 36.6)	1078	93 (8.6)	(7.0, 10.5)	496	46 (9.3)	(6.9, 12.2)
	Severe	1099	22 (2.0)	(1.3, 3.0)	490	21 (4.3)	(2.7, 6.5)	1078	1 (0.1)	(0.0, 0.5)	496	5 (1.0)	(0.3, 2.3)
	Grade 4	1099	0	(0.0, 0.3)	490	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Chills[e]												
	Any	1097	455 (41.5)	(38.5, 44.5)	489	196 (40.1)	(35.7, 44.6)	1079	74 (6.9)	(5.4, 8.5)	496	22 (4.4)	(2.8, 6.6)
	Mild	1097	221 (20.1)	(17.8, 22.6)	489	82 (16.8)	(13.6, 20.4)	1079	53 (4.9)	(3.7, 6.4)	496	17 (3.4)	(2.0, 5.4)
	Moderate	1097	214 (19.5)	(17.2, 22.0)	489	102 (20.9)	(17.3, 24.7)	1079	21 (1.9)	(1.2, 3.0)	496	5 (1.0)	(0.3, 2.3)
	Severe	1097	20 (1.8)	(1.1, 2.8)	489	12 (2.5)	(1.3, 4.2)	1079	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1097	0	(0.0, 0.3)	489	0	(0.0, 0.8)	1079	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Vomiting[f]												
	Any	1098	30 (2.7)	(1.9, 3.9)	488	13 (2.7)	(1.4, 4.5)	1078	12 (1.1)	(0.6, 1.9)	496	9 (1.8)	(0.8, 3.4)
	Mild	1098	26 (2.4)	(1.6, 3.5)	488	10 (2.0)	(1.0, 3.7)	1078	11 (1.0)	(0.5, 1.8)	496	5 (1.0)	(0.3, 2.3)
	Moderate	1098	4 (0.4)	(0.1, 0.9)	488	3 (0.6)	(0.1, 1.8)	1078	1 (0.1)	(0.0, 0.5)	496	4 (0.8)	(0.2, 2.1)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	1098	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1098	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Diarrhea[g]												
	Any	1098	67 (6.1)	(4.8, 7.7)	488	39 (8.0)	(5.7, 10.8)	1078	43 (4.0)	(2.9, 5.3)	497	27 (5.4)	(3.6, 7.8)
	Mild	1098	59 (5.4)	(4.1, 6.9)	488	32 (6.6)	(4.5, 9.1)	1078	38 (3.5)	(2.5, 4.8)	497	22 (4.4)	(2.8, 6.6)
	Moderate	1098	8 (0.7)	(0.3, 1.4)	488	5 (1.0)	(0.3, 2.4)	1078	5 (0.5)	(0.2, 1.1)	497	5 (1.0)	(0.3, 2.3)
	Severe	1098	0	(0.0, 0.3)	488	2 (0.4)	(0.0, 1.5)	1078	0	(0.0, 0.3)	497	0	(0.0, 0.7)
	Grade 4	1098	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	497	0	(0.0, 0.7)
	New or worsened muscle pain[e]												
	Any	1098	358 (32.6)	(29.8, 35.5)	489	201 (41.1)	(36.7, 45.6)	1078	91 (8.4)	(6.9, 10.3)	496	48 (9.7)	(7.2, 12.6)
	Mild	1098	154 (14.0)	(12.0, 16.2)	489	94 (19.2)	(15.8, 23.0)	1078	52 (4.8)	(3.6, 6.3)	496	29 (5.8)	(4.0, 8.3)
	Moderate	1098	198 (18.0)	(15.8, 20.4)	489	98 (20.0)	(16.6, 23.9)	1078	37 (3.4)	(2.4, 4.7)	496	18 (3.6)	(2.2, 5.7)
	Severe	1098	6 (0.5)	(0.2, 1.2)	489	9 (1.8)	(0.8, 3.5)	1078	2 (0.2)	(0.0, 0.7)	496	1 (0.2)	(0.0, 1.1)
	Grade 4	1098	0	(0.0, 0.3)	489	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	New or worsened joint pain[e]												
	Any	1097	173 (15.8)	(13.7, 18.1)	489	108 (22.1)	(18.5, 26.0)	1078	51 (4.7)	(3.5, 6.2)	496	20 (4.0)	(2.5, 6.2)
	Mild	1097	91 (8.3)	(6.7, 10.1)	489	50 (10.2)	(7.7, 13.3)	1078	30 (2.8)	(1.9, 3.9)	496	14 (2.8)	(1.6, 4.7)
	Moderate	1097	78 (7.1)	(5.7, 8.8)	489	54 (11.0)	(8.4, 14.2)	1078	21 (1.9)	(1.2, 3.0)	496	6 (1.2)	(0.4, 2.6)
	Severe	1097	4 (0.4)	(0.1, 0.9)	489	4 (0.8)	(0.2, 2.1)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Grade 4	1097	0	(0.0, 0.3)	489	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Any systemic event[h]	1101	910 (82.7)	(80.3, 84.8)	492	400 (81.3)	(77.6, 84.7)	1079	441 (40.9)	(37.9, 43.9)	497	184 (37.0)	(32.8, 41.4)
	Use of antipyretic or pain medication[i]	1097	557 (50.8)	(47.8, 53.8)	488	223 (45.7)	(41.2, 50.2)	1078	95 (8.8)	(7.2, 10.7)	496	59 (11.9)	(9.2, 15.1)
Any dose	Fever												
	Any	1131	277 (24.5)	(22.0, 27.1)	535	117 (21.9)	(18.4, 25.6)	1129	17 (1.5)	(0.9, 2.4)	555	9 (1.6)	(0.7, 3.1)
	≥38.0°C to 38.4°C	1131	141 (12.5)	(10.6, 14.5)	535	63 (11.8)	(9.2, 14.8)	1129	11 (1.0)	(0.5, 1.7)	555	6 (1.1)	(0.4, 2.3)
	>38.4°C to 38.9°C	1131	100 (8.8)	(7.3, 10.6)	535	40 (7.5)	(5.4, 10.0)	1129	3 (0.3)	(0.1, 0.8)	555	2 (0.4)	(0.0, 1.3)
	>38.9°C to 40.0°C	1131	33 (2.9)	(2.0, 4.1)	535	10 (1.9)	(0.9, 3.4)	1129	3 (0.3)	(0.1, 0.8)	555	1 (0.2)	(0.0, 1.0)
	>40.0°C	1131	1 (0.1)	(0.0, 0.5)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Unknown[d]	1131	2 (0.2)	(0.0, 0.6)	535	4 (0.7)	(0.2, 1.9)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Fatigue[e]												
	Any	1131	879 (77.7)	(75.2, 80.1)	535	403 (75.3)	(71.4, 78.9)	1129	538 (47.7)	(44.7, 50.6)	555	240 (43.2)	(39.1, 47.5)
	Mild	1131	240 (21.2)	(18.9, 23.7)	535	104 (19.4)	(16.2, 23.1)	1129	266 (23.6)	(21.1, 26.1)	555	114 (20.5)	(17.3, 24.1)
	Moderate	1131	599 (53.0)	(50.0, 55.9)	535	267 (49.9)	(45.6, 54.2)	1129	260 (23.0)	(20.6, 25.6)	555	119 (21.4)	(18.1, 25.1)
	Severe	1131	40 (3.5)	(2.5, 4.8)	535	32 (6.0)	(4.1, 8.3)	1129	12 (1.1)	(0.6, 1.8)	555	7 (1.3)	(0.5, 2.6)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Headache[e]												
	Any	1131	855 (75.6)	(73.0, 78.1)	535	387 (72.3)	(68.3, 76.1)	1129	506 (44.8)	(41.9, 47.8)	555	243 (43.8)	(39.6, 48.0)
	Mild	1131	323 (28.6)	(25.9, 31.3)	535	141 (26.4)	(22.7, 30.3)	1129	303 (26.8)	(24.3, 29.5)	555	147 (26.5)	(22.9, 30.4)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	1131	501 (44.3)	(41.4, 47.2)	535	216 (40.4)	(36.2, 44.7)	1129	194 (17.2)	(15.0, 19.5)	555	87 (15.7)	(12.8, 19.0)
	Severe	1131	31 (2.7)	(1.9, 3.9)	535	30 (5.6)	(3.8, 7.9)	1129	9 (0.8)	(0.4, 1.5)	555	9 (1.6)	(0.7, 3.1)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Chills[e]												
	Any	1131	557 (49.2)	(46.3, 52.2)	535	257 (48.0)	(43.7, 52.4)	1129	159 (14.1)	(12.1, 16.3)	555	60 (10.8)	(8.4, 13.7)
	Mild	1131	257 (22.7)	(20.3, 25.3)	535	117 (21.9)	(18.4, 25.6)	1129	114 (10.1)	(8.4, 12.0)	555	41 (7.4)	(5.4, 9.9)
	Moderate	1131	276 (24.4)	(21.9, 27.0)	535	124 (23.2)	(19.7, 27.0)	1129	43 (3.8)	(2.8, 5.1)	555	18 (3.2)	(1.9, 5.1)
	Severe	1131	24 (2.1)	(1.4, 3.1)	535	16 (3.0)	(1.7, 4.8)	1129	2 (0.2)	(0.0, 0.6)	555	1 (0.2)	(0.0, 1.0)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Vomiting[f]												
	Any	1131	60 (5.3)	(4.1, 6.8)	535	21 (3.9)	(2.4, 5.9)	1129	21 (1.9)	(1.2, 2.8)	555	16 (2.9)	(1.7, 4.6)
	Mild	1131	55 (4.9)	(3.7, 6.3)	535	18 (3.4)	(2.0, 5.3)	1129	18 (1.6)	(0.9, 2.5)	555	11 (2.0)	(1.0, 3.5)
	Moderate	1131	4 (0.4)	(0.1, 0.9)	535	3 (0.6)	(0.1, 1.6)	1129	3 (0.3)	(0.1, 0.8)	555	4 (0.7)	(0.2, 1.8)
	Severe	1131	1 (0.1)	(0.0, 0.5)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	1 (0.2)	(0.0, 1.0)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Diarrhea[g]												
	Any	1131	143 (12.6)	(10.8, 14.7)	535	81 (15.1)	(12.2, 18.5)	1129	107 (9.5)	(7.8, 11.3)	555	76 (13.7)	(10.9, 16.8)
	Mild	1131	123 (10.9)	(9.1, 12.8)	535	67 (12.5)	(9.8, 15.6)	1129	92 (8.1)	(6.6, 9.9)	555	58 (10.5)	(8.0, 13.3)
	Moderate	1131	20 (1.8)	(1.1, 2.7)	535	12 (2.2)	(1.2, 3.9)	1129	15 (1.3)	(0.7, 2.2)	555	18 (3.2)	(1.9, 5.1)
	Severe	1131	0	(0.0, 0.3)	535	2 (0.4)	(0.0, 1.3)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	New or worsened muscle pain[e]												
	Any	1131	479 (42.4)	(39.5, 45.3)	535	262 (49.0)	(44.7, 53.3)	1129	197 (17.4)	(15.3, 19.8)	555	103 (18.6)	(15.4, 22.0)
	Mild	1131	188 (16.6)	(14.5, 18.9)	535	107 (20.0)	(16.7, 23.6)	1129	111 (9.8)	(8.2, 11.7)	555	62 (11.2)	(8.7, 14.1)
	Moderate	1131	283 (25.0)	(22.5, 27.7)	535	141 (26.4)	(22.7, 30.3)	1129	84 (7.4)	(6.0, 9.1)	555	40 (7.2)	(5.2, 9.7)
	Severe	1131	8 (0.7)	(0.3, 1.4)	535	14 (2.6)	(1.4, 4.4)	1129	2 (0.2)	(0.0, 0.6)	555	1 (0.2)	(0.0, 1.0)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	New or worsened joint pain[e]												
	Any	1131	229 (20.2)	(17.9, 22.7)	535	142 (26.5)	(22.8, 30.5)	1129	107 (9.5)	(7.8, 11.3)	555	42 (7.6)	(5.5, 10.1)
	Mild	1131	122 (10.8)	(9.0, 12.7)	535	62 (11.6)	(9.0, 14.6)	1129	63 (5.6)	(4.3, 7.1)	555	26 (4.7)	(3.1, 6.8)
	Moderate	1131	102 (9.0)	(7.4, 10.8)	535	73 (13.6)	(10.9, 16.8)	1129	44 (3.9)	(2.8, 5.2)	555	16 (2.9)	(1.7, 4.6)
	Severe	1131	5 (0.4)	(0.1, 1.0)	535	7 (1.3)	(0.5, 2.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Any systemic event[h]	1131	1027 (90.8)	(89.0, 92.4)	535	473 (88.4)	(85.4, 91.0)	1129	726 (64.3)	(61.4, 67.1)	555	343 (61.8)	(57.6, 65.9)
	Use of antipyretic or pain medication[i]	1131	664 (58.7)	(55.8, 61.6)	535	279 (52.1)	(47.8, 56.5)	1129	176 (15.6)	(13.5, 17.8)	555	95 (17.1)	(14.1, 20.5)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person.

a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of subjects with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Only subjects with "Pyrexia, Body temperature increased" dictionary terms and non-missing AE toxicity grade recorded in AE and missing e-diary related

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

fever measurements, are counted in this row.

e. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe chills, severe muscle pain, or severe joint pain.

f. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.

g. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.

h. Any systemic event: any fever, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.

i. Severity was not collected for use of antipyretic or pain medication.

PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (21:11) Source Data: adfacevd Table Generation: 25JAN2022 (21:02)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_Peds_EDIARY/adce_s020_se_sev_ped_saf

**Duration (Days) From First to Last Day of Systemic Events –
Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	**Systemic Event**	**12-15 Years**	**16-25 Years**	**12-15 Years**	**16-25 Years**
1	Fever[a]				
	n[b]	114	39	12	8
	Mean (SD)	1.1 (0.48)	1.2 (0.54)	1.7 (1.37)	1.9 (2.27)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 4)	(1, 4)	(1, 5)	(1, 7)
	Unknown[c]	0	0	0	1
	Fatigue				
	n[b]	678	319	457	213
	Mean (SD)	2.5 (3.20)	2.5 (2.11)	3.1 (2.92)	3.0 (2.68)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 45)	(1, 11)	(1, 22)	(1, 15)
	Unknown[c]	0	0	2	3
	Headache				
	n[b]	624	288	396	205
	Mean (SD)	2.4 (2.27)	2.5 (2.50)	2.7 (2.55)	2.9 (3.17)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 24)	(1, 25)	(1, 21)	(1, 22)
	Unknown[c]	0	0	1	2
	Chills				
	n[b]	312	134	109	47
	Mean (SD)	1.6 (1.48)	1.5 (1.28)	2.6 (2.87)	2.3 (1.82)

Duration (Days) From First to Last Day of Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	**Systemic Event**	**12-15 Years**	**16-25 Years**	**12-15 Years**	**16-25 Years**
	Median	1.0	1.0	1.0	2.0
	Min, max	(1, 15)	(1, 8)	(1, 22)	(1, 7)
	Unknown[c]	1	1	2	1
	Vomiting				
	n[b]	31	9	10	9
	Mean (SD)	1.2 (0.88)	1.6 (1.33)	1.1 (0.32)	1.6 (1.13)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 5)	(1, 5)	(1, 2)	(1, 4)
	Diarrhea				
	n[b]	90	57	83	62
	Mean (SD)	1.6 (1.25)	1.7 (1.62)	1.7 (1.51)	1.7 (1.42)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 7)	(1, 9)	(1, 8)	(1, 7)
	New or worsened muscle pain				
	n[b]	272	144	148	78
	Mean (SD)	1.7 (1.28)	1.8 (1.65)	2.4 (3.02)	1.8 (1.95)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 9)	(1, 10)	(1, 22)	(1, 13)
	Unknown[c]	0	1	0	1
	New or worsened joint pain				
	n[b]	109	70	77	28
	Mean (SD)	1.6 (1.33)	1.7 (2.83)	2.2 (2.88)	2.7 (2.60)

Duration (Days) From First to Last Day of Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	**Systemic Event**	**12-15 Years**	**16-25 Years**	**12-15 Years**	**16-25 Years**
	Median	1.0	1.0	1.0	1.5
	Min, max	(1, 8)	(1, 24)	(1, 22)	(1, 12)
	Use of antipyretic or pain medication				
	n[b]	413	167	111	62
	Mean (SD)	1.6 (1.37)	1.7 (1.57)	2.1 (2.32)	3.2 (4.16)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 20)	(1, 10)	(1, 19)	(1, 23)
	Unknown[c]	0	0	1	2
2	Fever[a]				
	n[b]	217	88	7	2
	Mean (SD)	1.1 (0.38)	1.1 (0.41)	3.0 (4.86)	1.0 (NE)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 6)	(1, 3)	(1, 14)	(1, 1)
	Unknown[c]	1	0	0	1
	Fatigue				
	n[b]	732	323	265	116
	Mean (SD)	2.1 (1.92)	2.3 (2.43)	2.8 (3.05)	3.2 (4.37)
	Median	1.0	1.0	2.0	2.0
	Min, max	(1, 23)	(1, 28)	(1, 37)	(1, 38)
	Unknown[c]	4	3	2	4
	Headache				
	n[b]	710	300	263	118

Duration (Days) From First to Last Day of Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	**Systemic Event**	**12-15 Years**	**16-25 Years**	**12-15 Years**	**16-25 Years**
	Mean (SD)	2.1 (2.15)	2.2 (3.09)	2.5 (2.39)	3.5 (5.64)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 36)	(1, 42)	(1, 23)	(1, 35)
	Unknown[c]	6	1	3	3
	Chills				
	n[b]	455	196	74	22
	Mean (SD)	1.5 (1.07)	1.3 (0.90)	2.1 (1.89)	2.0 (1.41)
	Median	1.0	1.0	1.0	2.0
	Min, max	(1, 9)	(1, 11)	(1, 8)	(1, 6)
	Unknown[c]	1	1	1	1
	Vomiting				
	n[b]	30	13	12	9
	Mean (SD)	1.0 (0.18)	1.2 (0.38)	1.4 (0.90)	1.6 (1.67)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 2)	(1, 2)	(1, 4)	(1, 6)
	Diarrhea				
	n[b]	67	39	43	27
	Mean (SD)	2.1 (4.31)	1.4 (0.94)	1.5 (1.04)	4.2 (7.57)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 35)	(1, 5)	(1, 5)	(1, 33)
	Unknown[c]	1	0	1	1
	New or worsened muscle pain				

Duration (Days) From First to Last Day of Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Systemic Event	12-15 Years	16-25 Years	12-15 Years	16-25 Years
	n[b]	358	201	91	48
	Mean (SD)	1.7 (1.49)	1.6 (1.82)	2.1 (1.84)	2.3 (2.04)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 17)	(1, 23)	(1, 9)	(1, 9)
	Unknown[c]	1	1	0	0
	New or worsened joint pain				
	n[b]	173	108	51	20
	Mean (SD)	1.5 (1.26)	1.6 (2.74)	2.7 (2.61)	2.2 (1.81)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 8)	(1, 28)	(1, 12)	(1, 8)
	Unknown[c]	2	2	0	0
	Use of antipyretic or pain medication				
	n[b]	557	223	95	59
	Mean (SD)	1.6 (1.37)	1.8 (2.64)	1.9 (2.61)	2.1 (2.28)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 12)	(1, 28)	(1, 23)	(1, 15)
	Unknown[c]	3	0	2	2

Abbreviation: NE = not estimable.

Note: Duration was calculated in days as the difference from the start of the first reported event to the resolution of the last reported event, inclusive. For symptoms that are ongoing at the time of the next dose, stop date is computed as the next dose date.

Note: Events and use of antipyretic or pain medication were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. The resolution date for events lasting longer than 7 days was recorded on the subject's case report form.

a. Includes subjects with "Pyrexia, Body temperature increased" dictionary terms and non-missing AE toxicity grade recorded in AE, and subjects with

Duration (Days) From First to Last Day of Systemic Events –
Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	**Systemic Event**	**12-15 Years**	**16-25 Years**	**12-15 Years**	**16-25 Years**

temperature recorded in e-diary.
b. n = Number of subjects reporting the specified event on any of the 7 days, including subjects with events of unknown duration.
c. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (21:06) Source Data: adcevd Table Generation: 25JAN2022 (21:29)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_Peds_EDIARY/adce_s040_se_dur_ped_saf

Onset Days for Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	**Systemic Event**	**12-15 Years**	**16-25 Years**	**12-15 Years**	**16-25 Years**
1	Fever[a]				
	n[b]	114	39	12	8
	Mean (SD)	2.1 (0.37)	2.4 (1.29)	3.6 (2.02)	3.0 (2.00)
	Median	2.0	2.0	3.0	2.5
	Min, max	(1, 5)	(1, 7)	(1, 7)	(1, 7)
	Fatigue				
	n[b]	678	319	457	213
	Mean (SD)	1.8 (0.99)	1.9 (1.15)	2.0 (1.49)	2.3 (1.63)
	Median	2.0	2.0	1.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Headache				
	n[b]	624	288	396	205
	Mean (SD)	2.1 (1.21)	2.2 (1.37)	2.4 (1.69)	2.4 (1.58)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Chills				
	n[b]	312	134	109	47
	Mean (SD)	2.1 (1.00)	2.2 (1.19)	2.9 (1.75)	2.9 (1.91)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Vomiting				

Onset Days for Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	**Systemic Event**	**12-15 Years**	**16-25 Years**	**12-15 Years**	**16-25 Years**
	n[b]	31	9	10	9
	Mean (SD)	3.0 (1.67)	3.4 (2.13)	3.0 (1.83)	3.2 (1.48)
	Median	2.0	2.0	2.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 6)	(1, 5)
	Diarrhea				
	n[b]	90	57	83	62
	Mean (SD)	3.7 (1.79)	3.2 (1.48)	3.6 (1.86)	3.5 (1.81)
	Median	3.0	3.0	3.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	New or worsened muscle pain				
	n[b]	272	144	148	78
	Mean (SD)	2.1 (1.08)	2.2 (1.11)	2.5 (1.68)	3.0 (1.69)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	New or worsened joint pain				
	n[b]	109	70	77	28
	Mean (SD)	2.5 (1.41)	2.5 (1.32)	3.0 (1.92)	3.4 (1.79)
	Median	2.0	2.0	2.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Any systemic event[c]				
	n[b]	878	405	637	311
	Mean (SD)	1.8 (1.01)	1.8 (1.06)	2.0 (1.39)	2.1 (1.40)

Onset Days for Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	**Systemic Event**	**12-15 Years**	**16-25 Years**	**12-15 Years**	**16-25 Years**
	Median	2.0	2.0	1.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Use of antipyretic or pain medication				
	n[b]	413	167	111	62
	Mean (SD)	2.1 (0.91)	2.2 (1.03)	3.3 (1.93)	3.5 (1.90)
	Median	2.0	2.0	3.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
2	Fever[a]				
	n[b]	217	88	7	2
	Mean (SD)	2.0 (0.31)	2.0 (0.57)	3.0 (2.45)	1.5 (0.71)
	Median	2.0	2.0	2.0	1.5
	Min, max	(1, 4)	(1, 6)	(1, 7)	(1, 2)
	Fatigue				
	n[b]	732	323	265	116
	Mean (SD)	1.8 (0.67)	1.8 (0.79)	2.1 (1.59)	2.3 (1.48)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Headache				
	n[b]	710	300	263	118
	Mean (SD)	1.9 (0.66)	2.0 (0.91)	2.5 (1.68)	2.7 (1.83)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)

Onset Days for Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	**Systemic Event**	**12-15 Years**	**16-25 Years**	**12-15 Years**	**16-25 Years**
	Chills				
	n[b]	455	196	74	22
	Mean (SD)	2.0 (0.80)	1.9 (0.53)	2.8 (1.96)	3.0 (1.73)
	Median	2.0	2.0	2.0	3.0
	Min, max	(1, 7)	(1, 4)	(1, 7)	(1, 7)
	Vomiting				
	n[b]	30	13	12	9
	Mean (SD)	2.3 (1.12)	2.3 (0.85)	4.1 (1.62)	3.4 (2.35)
	Median	2.0	2.0	4.0	3.0
	Min, max	(1, 7)	(2, 5)	(2, 7)	(1, 7)
	Diarrhea				
	n[b]	67	39	43	27
	Mean (SD)	3.0 (1.57)	3.0 (1.48)	3.7 (2.06)	3.9 (2.03)
	Median	3.0	3.0	4.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	New or worsened muscle pain				
	n[b]	358	201	91	48
	Mean (SD)	2.1 (0.83)	2.0 (0.72)	2.8 (1.94)	2.8 (1.66)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	New or worsened joint pain				
	n[b]	173	108	51	20

Onset Days for Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	**Systemic Event**	**12-15 Years**	**16-25 Years**	**12-15 Years**	**16-25 Years**
	Mean (SD)	2.1 (0.77)	2.0 (0.68)	2.9 (1.81)	3.8 (2.07)
	Median	2.0	2.0	2.0	4.0
	Min, max	(1, 6)	(1, 7)	(1, 7)	(1, 7)
	Any systemic event[c]				
	n[b]	910	400	441	184
	Mean (SD)	1.8 (0.77)	1.8 (0.87)	2.3 (1.71)	2.2 (1.47)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Use of antipyretic or pain medication				
	n[b]	557	223	95	59
	Mean (SD)	2.0 (0.69)	2.0 (0.93)	3.2 (2.04)	3.0 (1.49)
	Median	2.0	2.0	3.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)

Note: Day of onset is the first day the specified event was reported.
a. Includes subjects with "Pyrexia, Body temperature increased" dictionary terms and non-missing AE toxicity grade recorded in AE, and subjects with temperature recorded in e-diary.
b. n = Number of subjects reporting the specified event, with each subject counted only once per event.
c. Any systemic event: any fever, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (21:11) Source Data: adfacevd Table Generation: 26JAN2022 (01:21)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_Peds_EDIARY/adce_s060_se_onset_ped_saf

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

					Rel Day[a]								
Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
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)

					Rel Day[a]								
Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	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
16-25	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
	C4591001 1150 11501152	2	23DEC2020	Pain at the injection site	Sev	Mod	Mild				N	25DEC2020	3

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

					Rel Day[a]								
Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	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
	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

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

					Rel Day[a]								
Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	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: 29APR2021 (21:11) Source Data: adfacevd Table Generation: 26JAN2022 (01:52)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_Peds_EDIARY/adce_l004_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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
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		
	C4591001 1007 10071626	2	20JAN2021	Oral temperature (°C)	36.8	39.1	36.7	36.6		36.7	36.9	21JAN2021	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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	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
	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

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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				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
	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

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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				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
	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

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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	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
	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

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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	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
				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

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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	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
	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

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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	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
	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
				Vomiting	N	N	Sev	N	N	N	N	23DEC2020	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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	C4591001 1140 11401345	2	11JAN2021	Oral temperature (°C)	36.2	38.9	36.4	35.7			36.8	12JAN2021	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
	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

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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	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		35.9		36.4	08JAN2021	3
	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

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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	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
	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	Sev*	Sev*	Sev*	Sev*	Sev*	Sev	Sev*	27DEC2020	7
				Headache	N	N	N	N		Sev	Sev*	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

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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				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
	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
16-25	C4591001 1001 10011125	1	04AUG2020	Fatigue	Mod	Mod	Sev	Mild			N	07AUG2020	4
				Headache	Mod	Mod	Sev	Mod			N	07AUG2020	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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
				New or worsened muscle pain	N	N	Sev	Sev*			N	07AUG2020	2
				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
	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

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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	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
	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

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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	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
	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

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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	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
	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

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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	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
	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		36.5	37.1		36.4	19NOV2020	2
	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

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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	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
	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

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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	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
	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

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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	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
				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

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

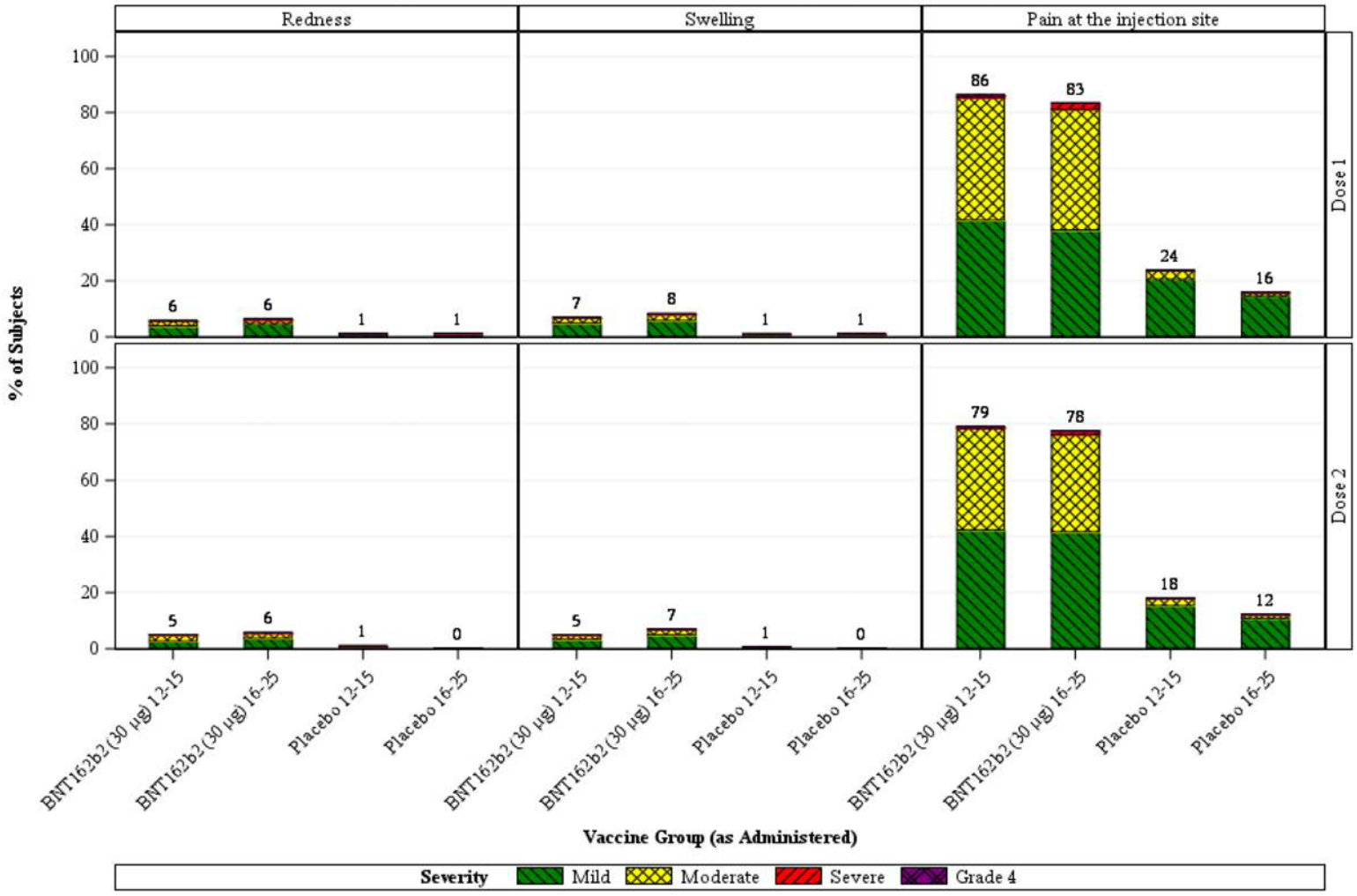
Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	C4591001 1231 12311306	1	15AUG2020	Headache	N	Mod	N	Sev	N	N	N	18AUG2020	3
	C4591001 1231 12311368	2	04SEP2020	Oral temperature (°C)	36	39.1	39.2	35.8	35.9	36.6	35.9	06SEP2020	2
	C4591001 1231 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] 1	2	3	4	5	6	7	Stop Date[b]	Dur (Days)[c]
	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

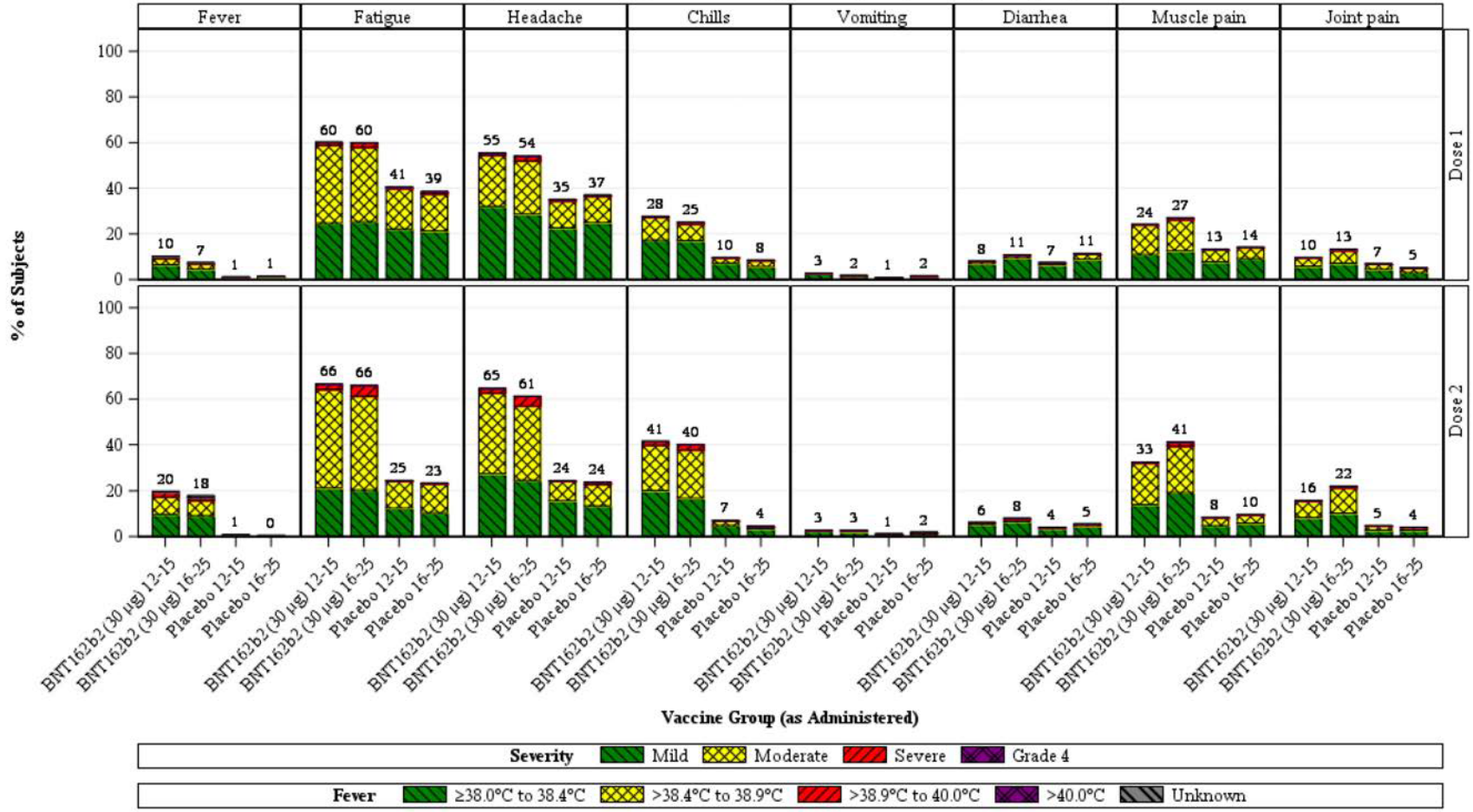
Abbreviations: Dur = duration; Mod = moderate; N = none; Sev = severe.
Note: Subject C4591001 1077 10771278 (13 years of age) experienced systemic events, including a temperature of 40.4°C, on the day of Dose 2. Since these events were recorded as adverse events and not in the electronic diary (e-diary), they do not appear in this listing.
Note: * = Systemic events recorded by the investigator on the AE log page.
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: 29APR2021 (21:11) Source Data: adfacevd Table Generation: 25JAN2022 (04:07)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 sBLA Peds EDIARY/adce l004 sevse ped

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose –
Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population



Note: Number above each bar denotes percentage of subjects reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (21:11) Source Data: adfacevd Table Generation: 25JAN2022 (02:21)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_Peds_EDIARY/adce_f001_lr_max_ped

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose –
Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population



Note: Number above each bar denotes percentage of subjects reporting the event with any severity.

Note: Only subjects with "Pyrexia, Body temperature increased" dictionary terms and non-missing AE toxicity grade recorded in AE and missing e-diary related fever measurements, are counted in "Unknown".

PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (21:11) Source Data: adfacevd Table Generation: 25JAN2022 (21:29)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_Peds_EDIARY/adce_f001_se_max_ped