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E-Diary Transmission (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) n[a] (%)	**Placebo** n[a] (%)
Vaccinated at Dose 1[b]	5033	5032
E-diary		
Not transmitted[c]	72 (1.4)	79 (1.6)
Transmitted[d]		
Day 1	4703 (93.4)	4657 (92.5)
Day 2	4733 (94.0)	4679 (93.0)
Day 3	4622 (91.8)	4674 (92.9)
Day 4	4583 (91.1)	4588 (91.2)
Day 5	4535 (90.1)	4582 (91.1)
Day 6	4562 (90.6)	4532 (90.1)
Day 7	4537 (90.1)	4548 (90.4)
All 7 days[e]	3454 (68.6)	3461 (68.8)
Vaccinated at Dose 2[b]	4964	4934
E-diary		
Not transmitted[c]	360 (7.3)	354 (7.2)
Transmitted[d]		
Day 1	3799 (76.5)	3615 (73.3)
Day 2	4249 (85.6)	3966 (80.4)
Day 3	4197 (84.5)	4063 (82.3)
Day 4	4162 (83.8)	4110 (83.3)
Day 5	4179 (84.2)	4132 (83.7)
Day 6	4182 (84.2)	4127 (83.6)
Day 7	4160 (83.8)	4155 (84.2)
All 7 days[e]	2718 (54.8)	2481 (50.3)

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E-Diary Transmission (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	Placebo
	n[a] (%)	n[a] (%)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
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 (22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:24)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_CBER_EDIARY/adce_s200_trns_p3_saf

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Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	55	3 (5.5)	(1.1, 15.1)	56	3 (5.4)	(1.1, 14.9)
	Mild	55	3 (5.5)	(1.1, 15.1)	56	1 (1.8)	(0.0, 9.6)
	Moderate	55	0	(0.0, 6.5)	56	0	(0.0, 6.4)
	Severe	55	0	(0.0, 6.5)	56	2 (3.6)	(0.4, 12.3)
	Grade 4	55	0	(0.0, 6.5)	56	0	(0.0, 6.4)
	Swelling[d]						
	Any	54	3 (5.6)	(1.2, 15.4)	56	1 (1.8)	(0.0, 9.6)
	Mild	54	2 (3.7)	(0.5, 12.7)	56	0	(0.0, 6.4)
	Moderate	54	1 (1.9)	(0.0, 9.9)	56	0	(0.0, 6.4)
	Severe	54	0	(0.0, 6.6)	56	1 (1.8)	(0.0, 9.6)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Pain at the injection site[e]						
	Any	57	38 (66.7)	(52.9, 78.6)	56	9 (16.1)	(7.6, 28.3)
	Mild	57	30 (52.6)	(39.0, 66.0)	56	8 (14.3)	(6.4, 26.2)
	Moderate	57	8 (14.0)	(6.3, 25.8)	56	1 (1.8)	(0.0, 9.6)
	Severe	57	0	(0.0, 6.3)	56	0	(0.0, 6.4)
	Grade 4	57	0	(0.0, 6.3)	56	0	(0.0, 6.4)
	Any local reaction[f]	57	39 (68.4)	(54.8, 80.1)	56	10 (17.9)	(8.9, 30.4)
2	Redness[d]						
	Any	60	4 (6.7)	(1.8, 16.2)	62	1 (1.6)	(0.0, 8.7)
	Mild	60	3 (5.0)	(1.0, 13.9)	62	1 (1.6)	(0.0, 8.7)

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Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	60	1 (1.7)	(0.0, 8.9)	62	0	(0.0, 5.8)
	Severe	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Grade 4	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Swelling[d]						
	Any	60	5 (8.3)	(2.8, 18.4)	62	0	(0.0, 5.8)
	Mild	60	2 (3.3)	(0.4, 11.5)	62	0	(0.0, 5.8)
	Moderate	60	3 (5.0)	(1.0, 13.9)	62	0	(0.0, 5.8)
	Severe	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Grade 4	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Pain at the injection site[e]						
	Any	61	33 (54.1)	(40.8, 66.9)	62	5 (8.1)	(2.7, 17.8)
	Mild	61	23 (37.7)	(25.6, 51.0)	62	5 (8.1)	(2.7, 17.8)
	Moderate	61	9 (14.8)	(7.0, 26.2)	62	0	(0.0, 5.8)
	Severe	61	1 (1.6)	(0.0, 8.8)	62	0	(0.0, 5.8)
	Grade 4	61	0	(0.0, 5.9)	62	0	(0.0, 5.8)
	Any local reaction[f]	61	33 (54.1)	(40.8, 66.9)	62	5 (8.1)	(2.7, 17.8)
Any dose	Redness[d]						
	Any	73	6 (8.2)	(3.1, 17.0)	74	3 (4.1)	(0.8, 11.4)
	Mild	73	5 (6.8)	(2.3, 15.3)	74	1 (1.4)	(0.0, 7.3)
	Moderate	73	1 (1.4)	(0.0, 7.4)	74	0	(0.0, 4.9)
	Severe	73	0	(0.0, 4.9)	74	2 (2.7)	(0.3, 9.4)
	Grade 4	73	0	(0.0, 4.9)	74	0	(0.0, 4.9)

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Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Swelling[d]						
	Any	72	7 (9.7)	(4.0, 19.0)	74	1 (1.4)	(0.0, 7.3)
	Mild	72	4 (5.6)	(1.5, 13.6)	74	0	(0.0, 4.9)
	Moderate	72	3 (4.2)	(0.9, 11.7)	74	0	(0.0, 4.9)
	Severe	72	0	(0.0, 5.0)	74	1 (1.4)	(0.0, 7.3)
	Grade 4	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	Pain at the injection site[e]						
	Any	74	54 (73.0)	(61.4, 82.6)	74	12 (16.2)	(8.7, 26.6)
	Mild	74	40 (54.1)	(42.1, 65.7)	74	11 (14.9)	(7.7, 25.0)
	Moderate	74	13 (17.6)	(9.7, 28.2)	74	1 (1.4)	(0.0, 7.3)
	Severe	74	1 (1.4)	(0.0, 7.3)	74	0	(0.0, 4.9)
	Grade 4	74	0	(0.0, 4.9)	74	0	(0.0, 4.9)
	Any local reaction[f]	74	54 (73.0)	(61.4, 82.6)	74	13 (17.6)	(9.7, 28.2)

Abbreviation: HIV = human immunodeficiency virus.
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 (22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:24)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 sBLA CBER EDIARY/adce s010 lr hiv p3 saf

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Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Positive	1	Redness[d]						
		Any	177	9 (5.1)	(2.4, 9.4)	187	5 (2.7)	(0.9, 6.1)
		Mild	177	3 (1.7)	(0.4, 4.9)	187	2 (1.1)	(0.1, 3.8)
		Moderate	177	4 (2.3)	(0.6, 5.7)	187	1 (0.5)	(0.0, 2.9)
		Severe	177	2 (1.1)	(0.1, 4.0)	187	2 (1.1)	(0.1, 3.8)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Swelling[d]						
		Any	177	14 (7.9)	(4.4, 12.9)	187	1 (0.5)	(0.0, 2.9)
		Mild	177	5 (2.8)	(0.9, 6.5)	187	0	(0.0, 2.0)
		Moderate	177	8 (4.5)	(2.0, 8.7)	187	0	(0.0, 2.0)
		Severe	177	1 (0.6)	(0.0, 3.1)	187	1 (0.5)	(0.0, 2.9)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Pain at the injection site[e]						
		Any	177	129 (72.9)	(65.7, 79.3)	187	25 (13.4)	(8.8, 19.1)
		Mild	177	71 (40.1)	(32.8, 47.7)	187	21 (11.2)	(7.1, 16.7)
		Moderate	177	54 (30.5)	(23.8, 37.9)	187	3 (1.6)	(0.3, 4.6)
		Severe	177	4 (2.3)	(0.6, 5.7)	187	1 (0.5)	(0.0, 2.9)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Any local reaction[f]	177	133 (75.1)	(68.1, 81.3)	187	27 (14.4)	(9.7, 20.3)
	2	Redness[d]						
		Any	153	6 (3.9)	(1.5, 8.3)	165	1 (0.6)	(0.0, 3.3)

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Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Mild	153	5 (3.3)	(1.1, 7.5)	165	0	(0.0, 2.2)
		Moderate	153	1 (0.7)	(0.0, 3.6)	165	0	(0.0, 2.2)
		Severe	153	0	(0.0, 2.4)	165	1 (0.6)	(0.0, 3.3)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Swelling[d]						
		Any	153	8 (5.2)	(2.3, 10.0)	165	1 (0.6)	(0.0, 3.3)
		Mild	153	3 (2.0)	(0.4, 5.6)	165	1 (0.6)	(0.0, 3.3)
		Moderate	153	5 (3.3)	(1.1, 7.5)	165	0	(0.0, 2.2)
		Severe	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Pain at the injection site[e]						
		Any	154	94 (61.0)	(52.9, 68.8)	165	11 (6.7)	(3.4, 11.6)
		Mild	154	54 (35.1)	(27.6, 43.2)	165	9 (5.5)	(2.5, 10.1)
		Moderate	154	34 (22.1)	(15.8, 29.5)	165	2 (1.2)	(0.1, 4.3)
		Severe	154	6 (3.9)	(1.4, 8.3)	165	0	(0.0, 2.2)
		Grade 4	154	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Any local reaction[f]	154	96 (62.3)	(54.2, 70.0)	165	12 (7.3)	(3.8, 12.4)
	Any dose	Redness[d]						
		Any	177	15 (8.5)	(4.8, 13.6)	187	5 (2.7)	(0.9, 6.1)
		Mild	177	8 (4.5)	(2.0, 8.7)	187	2 (1.1)	(0.1, 3.8)
		Moderate	177	5 (2.8)	(0.9, 6.5)	187	1 (0.5)	(0.0, 2.9)
		Severe	177	2 (1.1)	(0.1, 4.0)	187	2 (1.1)	(0.1, 3.8)

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Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Swelling[d]						
		Any	177	18 (10.2)	(6.1, 15.6)	187	2 (1.1)	(0.1, 3.8)
		Mild	177	6 (3.4)	(1.3, 7.2)	187	1 (0.5)	(0.0, 2.9)
		Moderate	177	11 (6.2)	(3.1, 10.8)	187	0	(0.0, 2.0)
		Severe	177	1 (0.6)	(0.0, 3.1)	187	1 (0.5)	(0.0, 2.9)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Pain at the injection site[e]						
		Any	177	142 (80.2)	(73.6, 85.8)	187	31 (16.6)	(11.6, 22.7)
		Mild	177	70 (39.5)	(32.3, 47.2)	187	25 (13.4)	(8.8, 19.1)
		Moderate	177	62 (35.0)	(28.0, 42.5)	187	5 (2.7)	(0.9, 6.1)
		Severe	177	10 (5.6)	(2.7, 10.1)	187	1 (0.5)	(0.0, 2.9)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Any local reaction[f]	177	145 (81.9)	(75.4, 87.3)	187	33 (17.6)	(12.5, 23.9)
Negative	1	Redness[d]						
		Any	4701	255 (5.4)	(4.8, 6.1)	4690	46 (1.0)	(0.7, 1.3)
		Mild	4701	183 (3.9)	(3.4, 4.5)	4690	33 (0.7)	(0.5, 1.0)
		Moderate	4701	62 (1.3)	(1.0, 1.7)	4690	10 (0.2)	(0.1, 0.4)
		Severe	4701	10 (0.2)	(0.1, 0.4)	4690	3 (0.1)	(0.0, 0.2)
		Grade 4	4701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Swelling[d]						
		Any	4701	310 (6.6)	(5.9, 7.3)	4690	40 (0.9)	(0.6, 1.2)

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Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Mild	4701	204 (4.3)	(3.8, 5.0)	4690	19 (0.4)	(0.2, 0.6)
		Moderate	4701	99 (2.1)	(1.7, 2.6)	4690	20 (0.4)	(0.3, 0.7)
		Severe	4701	7 (0.1)	(0.1, 0.3)	4690	1 (0.0)	(0.0, 0.1)
		Grade 4	4701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Pain at the injection site[e]						
		Any	4702	3685 (78.4)	(77.2, 79.5)	4690	579 (12.3)	(11.4, 13.3)
		Mild	4702	2487 (52.9)	(51.5, 54.3)	4690	552 (11.8)	(10.9, 12.7)
		Moderate	4702	1159 (24.6)	(23.4, 25.9)	4690	25 (0.5)	(0.3, 0.8)
		Severe	4702	39 (0.8)	(0.6, 1.1)	4690	2 (0.0)	(0.0, 0.2)
		Grade 4	4702	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Any local reaction[f]	4702	3725 (79.2)	(78.0, 80.4)	4690	620 (13.2)	(12.3, 14.2)
	2	Redness[d]						
		Any	4369	279 (6.4)	(5.7, 7.2)	4334	31 (0.7)	(0.5, 1.0)
		Mild	4369	149 (3.4)	(2.9, 4.0)	4334	22 (0.5)	(0.3, 0.8)
		Moderate	4369	109 (2.5)	(2.1, 3.0)	4334	9 (0.2)	(0.1, 0.4)
		Severe	4369	21 (0.5)	(0.3, 0.7)	4334	0	(0.0, 0.1)
		Grade 4	4369	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Swelling[d]						
		Any	4369	320 (7.3)	(6.6, 8.1)	4334	17 (0.4)	(0.2, 0.6)
		Mild	4369	187 (4.3)	(3.7, 4.9)	4334	7 (0.2)	(0.1, 0.3)
		Moderate	4369	122 (2.8)	(2.3, 3.3)	4334	9 (0.2)	(0.1, 0.4)
		Severe	4369	11 (0.3)	(0.1, 0.5)	4334	1 (0.0)	(0.0, 0.1)

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Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Grade 4	4369	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Pain at the injection site[e]						
		Any	4379	3238 (73.9)	(72.6, 75.2)	4336	450 (10.4)	(9.5, 11.3)
		Mild	4379	2096 (47.9)	(46.4, 49.4)	4336	419 (9.7)	(8.8, 10.6)
		Moderate	4379	1099 (25.1)	(23.8, 26.4)	4336	31 (0.7)	(0.5, 1.0)
		Severe	4379	43 (1.0)	(0.7, 1.3)	4336	0	(0.0, 0.1)
		Grade 4	4379	0	(0.0, 0.1)	4336	0	(0.0, 0.1)
		Any local reaction[f]	4379	3255 (74.3)	(73.0, 75.6)	4336	477 (11.0)	(10.1, 12.0)
	Any dose	Redness[d]						
		Any	4718	472 (10.0)	(9.2, 10.9)	4708	70 (1.5)	(1.2, 1.9)
		Mild	4718	291 (6.2)	(5.5, 6.9)	4708	48 (1.0)	(0.8, 1.3)
		Moderate	4718	150 (3.2)	(2.7, 3.7)	4708	19 (0.4)	(0.2, 0.6)
		Severe	4718	31 (0.7)	(0.4, 0.9)	4708	3 (0.1)	(0.0, 0.2)
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Swelling[d]						
		Any	4718	527 (11.2)	(10.3, 12.1)	4708	51 (1.1)	(0.8, 1.4)
		Mild	4718	321 (6.8)	(6.1, 7.6)	4708	22 (0.5)	(0.3, 0.7)
		Moderate	4718	188 (4.0)	(3.4, 4.6)	4708	27 (0.6)	(0.4, 0.8)
		Severe	4718	18 (0.4)	(0.2, 0.6)	4708	2 (0.0)	(0.0, 0.2)
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Pain at the injection site[e]						
		Any	4718	3992 (84.6)	(83.6, 85.6)	4708	826 (17.5)	(16.5, 18.7)

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Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Mild	4718	2275 (48.2)	(46.8, 49.7)	4708	772 (16.4)	(15.4, 17.5)
		Moderate	4718	1639 (34.7)	(33.4, 36.1)	4708	52 (1.1)	(0.8, 1.4)
		Severe	4718	78 (1.7)	(1.3, 2.1)	4708	2 (0.0)	(0.0, 0.2)
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Any local reaction[f]	4718	4022 (85.2)	(84.2, 86.2)	4708	880 (18.7)	(17.6, 19.8)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
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 (22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:24)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 sBLA CBER EDIARY/adce s010 lr base p3 saf

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Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
16-55 Years	1	Redness[d]						
		Any	2899	158 (5.5)	(4.7, 6.3)	2908	30 (1.0)	(0.7, 1.5)
		Mild	2899	115 (4.0)	(3.3, 4.7)	2908	21 (0.7)	(0.4, 1.1)
		Moderate	2899	36 (1.2)	(0.9, 1.7)	2908	6 (0.2)	(0.1, 0.4)
		Severe	2899	7 (0.2)	(0.1, 0.5)	2908	3 (0.1)	(0.0, 0.3)
		Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Swelling[d]						
		Any	2899	185 (6.4)	(5.5, 7.3)	2908	16 (0.6)	(0.3, 0.9)
		Mild	2899	124 (4.3)	(3.6, 5.1)	2908	6 (0.2)	(0.1, 0.4)
		Moderate	2899	55 (1.9)	(1.4, 2.5)	2908	8 (0.3)	(0.1, 0.5)
		Severe	2899	6 (0.2)	(0.1, 0.4)	2908	2 (0.1)	(0.0, 0.2)
		Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Pain at the injection site[e]						
		Any	2900	2428 (83.7)	(82.3, 85.1)	2908	418 (14.4)	(13.1, 15.7)
		Mild	2900	1464 (50.5)	(48.6, 52.3)	2908	395 (13.6)	(12.4, 14.9)
		Moderate	2900	924 (31.9)	(30.2, 33.6)	2908	20 (0.7)	(0.4, 1.1)
		Severe	2900	40 (1.4)	(1.0, 1.9)	2908	3 (0.1)	(0.0, 0.3)
		Grade 4	2900	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Any local reaction[f]	2900	2446 (84.3)	(83.0, 85.6)	2908	438 (15.1)	(13.8, 16.4)
	2	Redness[d]						
		Any	2683	152 (5.7)	(4.8, 6.6)	2684	18 (0.7)	(0.4, 1.1)
		Mild	2683	90 (3.4)	(2.7, 4.1)	2684	12 (0.4)	(0.2, 0.8)

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Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Moderate	2683	51 (1.9)	(1.4, 2.5)	2684	6 (0.2)	(0.1, 0.5)
		Severe	2683	11 (0.4)	(0.2, 0.7)	2684	0	(0.0, 0.1)
		Grade 4	2683	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Swelling[d]						
		Any	2683	185 (6.9)	(6.0, 7.9)	2684	5 (0.2)	(0.1, 0.4)
		Mild	2683	112 (4.2)	(3.4, 5.0)	2684	3 (0.1)	(0.0, 0.3)
		Moderate	2683	66 (2.5)	(1.9, 3.1)	2684	2 (0.1)	(0.0, 0.3)
		Severe	2683	7 (0.3)	(0.1, 0.5)	2684	0	(0.0, 0.1)
		Grade 4	2683	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Pain at the injection site[e]						
		Any	2691	2110 (78.4)	(76.8, 80.0)	2684	315 (11.7)	(10.5, 13.0)
		Mild	2691	1280 (47.6)	(45.7, 49.5)	2684	287 (10.7)	(9.5, 11.9)
		Moderate	2691	791 (29.4)	(27.7, 31.2)	2684	28 (1.0)	(0.7, 1.5)
		Severe	2691	39 (1.4)	(1.0, 2.0)	2684	0	(0.0, 0.1)
		Grade 4	2691	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Any local reaction[f]	2691	2117 (78.7)	(77.1, 80.2)	2684	328 (12.2)	(11.0, 13.5)
	Any dose	Redness[d]						
		Any	2909	278 (9.6)	(8.5, 10.7)	2921	44 (1.5)	(1.1, 2.0)
		Mild	2909	181 (6.2)	(5.4, 7.2)	2921	29 (1.0)	(0.7, 1.4)
		Moderate	2909	79 (2.7)	(2.2, 3.4)	2921	12 (0.4)	(0.2, 0.7)
		Severe	2909	18 (0.6)	(0.4, 1.0)	2921	3 (0.1)	(0.0, 0.3)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)

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Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Swelling[d]						
		Any	2909	312 (10.7)	(9.6, 11.9)	2921	20 (0.7)	(0.4, 1.1)
		Mild	2909	197 (6.8)	(5.9, 7.7)	2921	9 (0.3)	(0.1, 0.6)
		Moderate	2909	102 (3.5)	(2.9, 4.2)	2921	9 (0.3)	(0.1, 0.6)
		Severe	2909	13 (0.4)	(0.2, 0.8)	2921	2 (0.1)	(0.0, 0.2)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		Pain at the injection site[e]						
		Any	2909	2579 (88.7)	(87.4, 89.8)	2921	590 (20.2)	(18.8, 21.7)
		Mild	2909	1279 (44.0)	(42.2, 45.8)	2921	543 (18.6)	(17.2, 20.0)
		Moderate	2909	1225 (42.1)	(40.3, 43.9)	2921	44 (1.5)	(1.1, 2.0)
		Severe	2909	75 (2.6)	(2.0, 3.2)	2921	3 (0.1)	(0.0, 0.3)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		Any local reaction[f]	2909	2592 (89.1)	(87.9, 90.2)	2921	615 (21.1)	(19.6, 22.6)
>55 Years	1	Redness[d]						
		Any	2008	109 (5.4)	(4.5, 6.5)	1989	21 (1.1)	(0.7, 1.6)
		Mild	2008	74 (3.7)	(2.9, 4.6)	1989	14 (0.7)	(0.4, 1.2)
		Moderate	2008	30 (1.5)	(1.0, 2.1)	1989	5 (0.3)	(0.1, 0.6)
		Severe	2008	5 (0.2)	(0.1, 0.6)	1989	2 (0.1)	(0.0, 0.4)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Swelling[d]						
		Any	2008	142 (7.1)	(6.0, 8.3)	1989	25 (1.3)	(0.8, 1.8)
		Mild	2008	88 (4.4)	(3.5, 5.4)	1989	13 (0.7)	(0.3, 1.1)
		Moderate	2008	52 (2.6)	(1.9, 3.4)	1989	12 (0.6)	(0.3, 1.1)

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Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Severe	2008	2 (0.1)	(0.0, 0.4)	1989	0	(0.0, 0.2)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Pain at the injection site[e]						
		Any	2008	1409 (70.2)	(68.1, 72.2)	1989	187 (9.4)	(8.2, 10.8)
		Mild	2008	1109 (55.2)	(53.0, 57.4)	1989	179 (9.0)	(7.8, 10.3)
		Moderate	2008	296 (14.7)	(13.2, 16.4)	1989	8 (0.4)	(0.2, 0.8)
		Severe	2008	4 (0.2)	(0.1, 0.5)	1989	0	(0.0, 0.2)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Any local reaction[f]	2008	1435 (71.5)	(69.4, 73.4)	1989	210 (10.6)	(9.2, 12.0)
	2	Redness[d]						
		Any	1860	134 (7.2)	(6.1, 8.5)	1833	14 (0.8)	(0.4, 1.3)
		Mild	1860	65 (3.5)	(2.7, 4.4)	1833	10 (0.5)	(0.3, 1.0)
		Moderate	1860	59 (3.2)	(2.4, 4.1)	1833	3 (0.2)	(0.0, 0.5)
		Severe	1860	10 (0.5)	(0.3, 1.0)	1833	1 (0.1)	(0.0, 0.3)
		Grade 4	1860	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		Swelling[d]						
		Any	1860	145 (7.8)	(6.6, 9.1)	1833	13 (0.7)	(0.4, 1.2)
		Mild	1860	80 (4.3)	(3.4, 5.3)	1833	5 (0.3)	(0.1, 0.6)
		Moderate	1860	61 (3.3)	(2.5, 4.2)	1833	7 (0.4)	(0.2, 0.8)
		Severe	1860	4 (0.2)	(0.1, 0.5)	1833	1 (0.1)	(0.0, 0.3)
		Grade 4	1860	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		Pain at the injection site[e]						

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Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	1863	1236 (66.3)	(64.1, 68.5)	1835	147 (8.0)	(6.8, 9.3)
		Mild	1863	879 (47.2)	(44.9, 49.5)	1835	142 (7.7)	(6.6, 9.1)
		Moderate	1863	347 (18.6)	(16.9, 20.5)	1835	5 (0.3)	(0.1, 0.6)
		Severe	1863	10 (0.5)	(0.3, 1.0)	1835	0	(0.0, 0.2)
		Grade 4	1863	0	(0.0, 0.2)	1835	0	(0.0, 0.2)
		Any local reaction[f]	1863	1248 (67.0)	(64.8, 69.1)	1835	162 (8.8)	(7.6, 10.2)
	Any dose	Redness[d]						
		Any	2015	213 (10.6)	(9.3, 12.0)	1994	31 (1.6)	(1.1, 2.2)
		Mild	2015	122 (6.1)	(5.1, 7.2)	1994	21 (1.1)	(0.7, 1.6)
		Moderate	2015	76 (3.8)	(3.0, 4.7)	1994	8 (0.4)	(0.2, 0.8)
		Severe	2015	15 (0.7)	(0.4, 1.2)	1994	2 (0.1)	(0.0, 0.4)
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		Swelling[d]						
		Any	2015	238 (11.8)	(10.4, 13.3)	1994	33 (1.7)	(1.1, 2.3)
		Mild	2015	135 (6.7)	(5.6, 7.9)	1994	14 (0.7)	(0.4, 1.2)
		Moderate	2015	97 (4.8)	(3.9, 5.8)	1994	18 (0.9)	(0.5, 1.4)
		Severe	2015	6 (0.3)	(0.1, 0.6)	1994	1 (0.1)	(0.0, 0.3)
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		Pain at the injection site[e]						
		Any	2015	1579 (78.4)	(76.5, 80.1)	1994	269 (13.5)	(12.0, 15.1)
		Mild	2015	1079 (53.5)	(51.3, 55.7)	1994	256 (12.8)	(11.4, 14.4)
		Moderate	2015	486 (24.1)	(22.3, 26.0)	1994	13 (0.7)	(0.3, 1.1)
		Severe	2015	14 (0.7)	(0.4, 1.2)	1994	0	(0.0, 0.2)

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Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		Any local reaction[f]	2015	1599 (79.4)	(77.5, 81.1)	1994	300 (15.0)	(13.5, 16.7)

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 (22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:24)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 sBLA CBER EDIARY/adce s010 lr p3 saf

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Duration (Days) From First to Last Day of Local Reactions (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
1	Redness		
	n[a]	3	3
	Mean (SD)	1.7 (0.58)	1.0 (0.00)
	Median	2.0	1.0
	Min, max	(1, 2)	(1, 1)
	Swelling		
	n[a]	3	1
	Mean (SD)	1.3 (0.58)	1.0 (NE)
	Median	1.0	1.0
	Min, max	(1, 2)	(1, 1)
	Pain at the injection site		
	n[a]	38	9
	Mean (SD)	2.0 (1.14)	1.9 (1.36)
	Median	2.0	1.0
	Min, max	(1, 7)	(1, 5)
2	Redness		
	n[a]	4	1
	Mean (SD)	1.3 (0.50)	2.0 (NE)
	Median	1.0	2.0
	Min, max	(1, 2)	(2, 2)
	Swelling		
	n[a]	5	0
	Mean (SD)	1.8 (0.84)	NE (NE)

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Duration (Days) From First to Last Day of Local Reactions (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
	Median	2.0	NE
	Min, max	(1, 3)	(NE, NE)
	Pain at the injection site		
	n[a]	33	5
	Mean (SD)	1.9 (1.17)	2.0 (1.41)
	Median	1.0	1.0
	Min, max	(1, 5)	(1, 4)

Abbreviations: HIV = human immunodeficiency virus; 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.
PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (22:06) Source Data: adcevd Table Generation: 29APR2021 (23:34)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2_unblinded/C4591001_sBLA_CBER_EDIARY/adce_s030_lr_dur_hiv_p3_saf

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Duration (Days) From First to Last Day of Local Reactions, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
16-55 Years	1	Redness		
		n[a]	158	30
		Mean (SD)	2.3 (1.99)	1.7 (1.35)
		Median	1.5	1.0
		Min, max	(1, 14)	(1, 6)
		Swelling		
		n[a]	185	16
		Mean (SD)	2.0 (1.55)	2.2 (2.46)
		Median	1.0	1.0
		Min, max	(1, 12)	(1, 10)
		Pain at the injection site		
		n[a]	2428	418
		Mean (SD)	2.2 (1.49)	1.5 (1.50)
		Median	2.0	1.0
		Min, max	(1, 22)	(1, 17)
		Unknown[b]	2	1
	2	Redness		
		n[a]	152	18
		Mean (SD)	2.2 (1.60)	1.2 (0.43)
		Median	2.0	1.0
		Min, max	(1, 9)	(1, 2)
		Swelling		
		n[a]	185	5

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Duration (Days) From First to Last Day of Local Reactions, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
		Mean (SD)	2.1 (1.49)	2.2 (0.84)
		Median	2.0	2.0
		Min, max	(1, 8)	(1, 3)
		Pain at the injection site		
		n[a]	2110	315
		Mean (SD)	2.5 (2.20)	1.9 (2.82)
		Median	2.0	1.0
		Min, max	(1, 70)	(1, 35)
		Unknown[b]	5	0
>55 Years	1	Redness		
		n[a]	109	21
		Mean (SD)	2.4 (2.36)	1.9 (2.06)
		Median	2.0	1.0
		Min, max	(1, 20)	(1, 10)
		Swelling		
		n[a]	142	25
		Mean (SD)	1.7 (1.03)	2.8 (2.84)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 11)
		Pain at the injection site		
		n[a]	1409	187
		Mean (SD)	1.9 (1.46)	1.8 (2.15)
		Median	2.0	1.0
		Min, max	(1, 22)	(1, 19)

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Duration (Days) From First to Last Day of Local Reactions, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
	2	Redness		
		n[a]	134	14
		Mean (SD)	3.0 (3.91)	1.6 (1.65)
		Median	2.0	1.0
		Min, max	(1, 34)	(1, 7)
		Unknown[b]	3	0
		Swelling		
		n[a]	145	13
		Mean (SD)	2.6 (3.21)	1.8 (1.28)
		Median	2.0	1.0
		Min, max	(1, 34)	(1, 5)
		Pain at the injection site		
		n[a]	1236	147
		Mean (SD)	2.4 (1.98)	1.9 (2.65)
		Median	2.0	1.0
		Min, max	(1, 36)	(1, 30)
		Unknown[b]	3	1

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 (22:06) Source Data: adcevd Table Generation: 29APR2021 (23:34)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 sBLA CBER EDIARY/adce s030 lr dur p3 saf

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**Onset Days for Local Reactions (Reactogenicity Subset) –
Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population**

		Vaccine Group (as Administered)	
Dose	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
1	Redness		
	n[a]	3	3
	Mean (SD)	1.7 (0.58)	1.0 (0.00)
	Median	2.0	1.0
	Min, max	(1, 2)	(1, 1)
	Swelling		
	n[a]	3	1
	Mean (SD)	2.0 (0.00)	2.0 (NE)
	Median	2.0	2.0
	Min, max	(2, 2)	(2, 2)
	Pain at the injection site		
	n[a]	38	9
	Mean (SD)	1.4 (0.50)	2.6 (1.24)
	Median	1.0	2.0
	Min, max	(1, 2)	(1, 5)
	Any local reaction[b]		
	n[a]	39	10
	Mean (SD)	1.4 (0.50)	1.9 (0.99)
	Median	1.0	2.0
	Min, max	(1, 2)	(1, 4)
2	Redness		
	n[a]	4	1
	Mean (SD)	2.0 (0.82)	1.0 (NE)

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**Onset Days for Local Reactions (Reactogenicity Subset) –
Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population**

		Vaccine Group (as Administered)	
Dose	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
	Median	2.0	1.0
	Min, max	(1, 3)	(1, 1)
	Swelling		
	n[a]	5	0
	Mean (SD)	1.4 (0.55)	NE (NE)
	Median	1.0	NE
	Min, max	(1, 2)	(NE, NE)
	Pain at the injection site		
	n[a]	33	5
	Mean (SD)	1.5 (0.67)	1.6 (0.89)
	Median	1.0	1.0
	Min, max	(1, 3)	(1, 3)
	Any local reaction[b]		
	n[a]	33	5
	Mean (SD)	1.5 (0.67)	1.6 (0.89)
	Median	1.0	1.0
	Min, max	(1, 3)	(1, 3)

Abbreviations: HIV = human immunodeficiency virus; 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.
PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:22)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2_unblinded/C4591001_sBLA_CBER_EDIARY/adce_s050_lr_onset_hiv_p3_saf

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Onset Days for Local Reactions, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
16-55 Years	1	Redness		
		n[a]	158	30
		Mean (SD)	2.3 (0.98)	1.8 (1.27)
		Median	2.0	1.0
		Min, max	(1, 7)	(1, 5)
		Swelling		
		n[a]	185	16
		Mean (SD)	2.0 (0.80)	1.8 (1.29)
		Median	2.0	1.0
		Min, max	(1, 5)	(1, 5)
		Pain at the injection site		
		n[a]	2428	418
		Mean (SD)	1.4 (0.55)	1.6 (1.15)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 7)
		Any local reaction[b]		
		n[a]	2446	438
		Mean (SD)	1.4 (0.55)	1.6 (1.14)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 7)
	2	Redness		
		n[a]	152	18
		Mean (SD)	2.5 (0.98)	2.2 (1.50)

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Onset Days for Local Reactions, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
		Median	2.0	2.0
		Min, max	(1, 6)	(1, 6)
		Swelling		
		n[a]	185	5
		Mean (SD)	2.0 (0.86)	2.0 (1.00)
		Median	2.0	2.0
		Min, max	(1, 5)	(1, 3)
		Pain at the injection site		
		n[a]	2110	315
		Mean (SD)	1.4 (0.59)	1.4 (0.95)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 7)
		Any local reaction[b]		
		n[a]	2117	328
		Mean (SD)	1.4 (0.59)	1.5 (1.01)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 7)
>55 Years	1	Redness		
		n[a]	109	21
		Mean (SD)	2.3 (0.82)	1.6 (0.51)
		Median	2.0	2.0
		Min, max	(1, 5)	(1, 2)
		Swelling		

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Onset Days for Local Reactions, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
		n[a]	142	25
		Mean (SD)	1.9 (0.58)	1.5 (0.87)
		Median	2.0	1.0
		Min, max	(1, 4)	(1, 4)
		Pain at the injection site		
		n[a]	1409	187
		Mean (SD)	1.6 (0.53)	1.8 (1.20)
		Median	2.0	1.0
		Min, max	(1, 5)	(1, 7)
		Any local reaction[b]		
		n[a]	1435	210
		Mean (SD)	1.6 (0.53)	1.8 (1.14)
		Median	2.0	1.0
		Min, max	(1, 5)	(1, 7)
	2	Redness		
		n[a]	134	14
		Mean (SD)	2.7 (1.04)	2.0 (1.30)
		Median	3.0	2.0
		Min, max	(1, 5)	(1, 6)
		Swelling		
		n[a]	145	13
		Mean (SD)	2.1 (0.83)	1.7 (1.18)
		Median	2.0	1.0
		Min, max	(1, 5)	(1, 5)

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Onset Days for Local Reactions, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Local Reaction**	**BNT162b2 (30 µg)**	**Placebo**
		Pain at the injection site		
		n[a]	1236	147
		Mean (SD)	1.5 (0.68)	1.7 (1.18)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 7)
		Any local reaction[b]		
		n[a]	1248	162
		Mean (SD)	1.5 (0.66)	1.7 (1.21)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 7)

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.
PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:22)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_CBER_EDIARY/adce_s050_lr_onset_p3_saf

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	Any	54	2 (3.7)	(0.5, 12.7)	56	4 (7.1)	(2.0, 17.3)
	≥38.0°C to 38.4°C	54	1 (1.9)	(0.0, 9.9)	56	2 (3.6)	(0.4, 12.3)
	>38.4°C to 38.9°C	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	>38.9°C to 40.0°C	54	0	(0.0, 6.6)	56	2 (3.6)	(0.4, 12.3)
	>40.0°C	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Unknown[d]	54	1 (1.9)	(0.0, 9.9)	56	0	(0.0, 6.4)
	Fatigue[e]						
	Any	54	22 (40.7)	(27.6, 55.0)	56	15 (26.8)	(15.8, 40.3)
	Mild	54	15 (27.8)	(16.5, 41.6)	56	9 (16.1)	(7.6, 28.3)
	Moderate	54	7 (13.0)	(5.4, 24.9)	56	5 (8.9)	(3.0, 19.6)
	Severe	54	0	(0.0, 6.6)	56	1 (1.8)	(0.0, 9.6)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Headache[e]						
	Any	54	11 (20.4)	(10.6, 33.5)	56	18 (32.1)	(20.3, 46.0)
	Mild	54	7 (13.0)	(5.4, 24.9)	56	10 (17.9)	(8.9, 30.4)
	Moderate	54	4 (7.4)	(2.1, 17.9)	56	7 (12.5)	(5.2, 24.1)
	Severe	54	0	(0.0, 6.6)	56	1 (1.8)	(0.0, 9.6)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Chills[e]						
	Any	54	6 (11.1)	(4.2, 22.6)	56	5 (8.9)	(3.0, 19.6)
	Mild	54	5 (9.3)	(3.1, 20.3)	56	4 (7.1)	(2.0, 17.3)
	Moderate	54	1 (1.9)	(0.0, 9.9)	56	1 (1.8)	(0.0, 9.6)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Vomiting[f]						
	Any	54	1 (1.9)	(0.0, 9.9)	56	3 (5.4)	(1.1, 14.9)
	Mild	54	1 (1.9)	(0.0, 9.9)	56	1 (1.8)	(0.0, 9.6)
	Moderate	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Severe	54	0	(0.0, 6.6)	56	2 (3.6)	(0.4, 12.3)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Diarrhea[g]						
	Any	54	5 (9.3)	(3.1, 20.3)	56	8 (14.3)	(6.4, 26.2)
	Mild	54	5 (9.3)	(3.1, 20.3)	56	6 (10.7)	(4.0, 21.9)
	Moderate	54	0	(0.0, 6.6)	56	1 (1.8)	(0.0, 9.6)
	Severe	54	0	(0.0, 6.6)	56	1 (1.8)	(0.0, 9.6)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	New or worsened muscle pain[e]						
	Any	55	10 (18.2)	(9.1, 30.9)	56	10 (17.9)	(8.9, 30.4)
	Mild	55	7 (12.7)	(5.3, 24.5)	56	7 (12.5)	(5.2, 24.1)
	Moderate	55	3 (5.5)	(1.1, 15.1)	56	3 (5.4)	(1.1, 14.9)
	Severe	55	0	(0.0, 6.5)	56	0	(0.0, 6.4)
	Grade 4	55	0	(0.0, 6.5)	56	0	(0.0, 6.4)
	New or worsened joint pain[e]						
	Any	54	5 (9.3)	(3.1, 20.3)	56	7 (12.5)	(5.2, 24.1)
	Mild	54	5 (9.3)	(3.1, 20.3)	56	4 (7.1)	(2.0, 17.3)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	54	0	(0.0, 6.6)	56	3 (5.4)	(1.1, 14.9)
	Severe	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Grade 4	54	0	(0.0, 6.6)	56	0	(0.0, 6.4)
	Any systemic event[h]	55	33 (60.0)	(45.9, 73.0)	56	32 (57.1)	(43.2, 70.3)
	Use of antipyretic or pain medication[i]	54	7 (13.0)	(5.4, 24.9)	56	8 (14.3)	(6.4, 26.2)
2	Fever						
	Any	61	13 (21.3)	(11.9, 33.7)	62	5 (8.1)	(2.7, 17.8)
	≥38.0°C to 38.4°C	61	4 (6.6)	(1.8, 15.9)	62	5 (8.1)	(2.7, 17.8)
	>38.4°C to 38.9°C	61	4 (6.6)	(1.8, 15.9)	62	0	(0.0, 5.8)
	>38.9°C to 40.0°C	61	1 (1.6)	(0.0, 8.8)	62	0	(0.0, 5.8)
	>40.0°C	61	0	(0.0, 5.9)	62	0	(0.0, 5.8)
	Unknown[d]	61	4 (6.6)	(1.8, 15.9)	62	0	(0.0, 5.8)
	Fatigue[e]						
	Any	62	26 (41.9)	(29.5, 55.2)	63	13 (20.6)	(11.5, 32.7)
	Mild	62	14 (22.6)	(12.9, 35.0)	63	6 (9.5)	(3.6, 19.6)
	Moderate	62	9 (14.5)	(6.9, 25.8)	63	7 (11.1)	(4.6, 21.6)
	Severe	62	3 (4.8)	(1.0, 13.5)	63	0	(0.0, 5.7)
	Grade 4	62	0	(0.0, 5.8)	63	0	(0.0, 5.7)
	Headache[e]						
	Any	61	19 (31.1)	(19.9, 44.3)	62	12 (19.4)	(10.4, 31.4)
	Mild	61	9 (14.8)	(7.0, 26.2)	62	8 (12.9)	(5.7, 23.9)
	Moderate	61	8 (13.1)	(5.8, 24.2)	62	4 (6.5)	(1.8, 15.7)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	61	2 (3.3)	(0.4, 11.3)	62	0	(0.0, 5.8)
	Grade 4	61	0	(0.0, 5.9)	62	0	(0.0, 5.8)
	Chills[e]						
	Any	61	16 (26.2)	(15.8, 39.1)	62	4 (6.5)	(1.8, 15.7)
	Mild	61	6 (9.8)	(3.7, 20.2)	62	3 (4.8)	(1.0, 13.5)
	Moderate	61	8 (13.1)	(5.8, 24.2)	62	1 (1.6)	(0.0, 8.7)
	Severe	61	2 (3.3)	(0.4, 11.3)	62	0	(0.0, 5.8)
	Grade 4	61	0	(0.0, 5.9)	62	0	(0.0, 5.8)
	Vomiting[f]						
	Any	60	2 (3.3)	(0.4, 11.5)	62	2 (3.2)	(0.4, 11.2)
	Mild	60	1 (1.7)	(0.0, 8.9)	62	1 (1.6)	(0.0, 8.7)
	Moderate	60	0	(0.0, 6.0)	62	1 (1.6)	(0.0, 8.7)
	Severe	60	1 (1.7)	(0.0, 8.9)	62	0	(0.0, 5.8)
	Grade 4	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Diarrhea[g]						
	Any	60	4 (6.7)	(1.8, 16.2)	62	9 (14.5)	(6.9, 25.8)
	Mild	60	1 (1.7)	(0.0, 8.9)	62	6 (9.7)	(3.6, 19.9)
	Moderate	60	2 (3.3)	(0.4, 11.5)	62	3 (4.8)	(1.0, 13.5)
	Severe	60	1 (1.7)	(0.0, 8.9)	62	0	(0.0, 5.8)
	Grade 4	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	New or worsened muscle pain[e]						
	Any	61	12 (19.7)	(10.6, 31.8)	62	5 (8.1)	(2.7, 17.8)
	Mild	61	7 (11.5)	(4.7, 22.2)	62	1 (1.6)	(0.0, 8.7)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	61	4 (6.6)	(1.8, 15.9)	62	4 (6.5)	(1.8, 15.7)
	Severe	61	1 (1.6)	(0.0, 8.8)	62	0	(0.0, 5.8)
	Grade 4	61	0	(0.0, 5.9)	62	0	(0.0, 5.8)
	New or worsened joint pain[e]						
	Any	61	11 (18.0)	(9.4, 30.0)	62	5 (8.1)	(2.7, 17.8)
	Mild	61	5 (8.2)	(2.7, 18.1)	62	1 (1.6)	(0.0, 8.7)
	Moderate	61	6 (9.8)	(3.7, 20.2)	62	4 (6.5)	(1.8, 15.7)
	Severe	61	0	(0.0, 5.9)	62	0	(0.0, 5.8)
	Grade 4	61	0	(0.0, 5.9)	62	0	(0.0, 5.8)
	Any systemic event[h]	62	39 (62.9)	(49.7, 74.8)	63	24 (38.1)	(26.1, 51.2)
	Use of antipyretic or pain medication[i]	60	16 (26.7)	(16.1, 39.7)	62	7 (11.3)	(4.7, 21.9)
Any dose	Fever						
	Any	73	14 (19.2)	(10.9, 30.1)	74	7 (9.5)	(3.9, 18.5)
	≥38.0°C to 38.4°C	73	4 (5.5)	(1.5, 13.4)	74	5 (6.8)	(2.2, 15.1)
	>38.4°C to 38.9°C	73	4 (5.5)	(1.5, 13.4)	74	0	(0.0, 4.9)
	>38.9°C to 40.0°C	73	1 (1.4)	(0.0, 7.4)	74	2 (2.7)	(0.3, 9.4)
	>40.0°C	73	0	(0.0, 4.9)	74	0	(0.0, 4.9)
	Unknown[d]	73	5 (6.8)	(2.3, 15.3)	74	0	(0.0, 4.9)
	Fatigue[e]						
	Any	74	36 (48.6)	(36.9, 60.6)	75	21 (28.0)	(18.2, 39.6)
	Mild	74	20 (27.0)	(17.4, 38.6)	75	9 (12.0)	(5.6, 21.6)
	Moderate	74	13 (17.6)	(9.7, 28.2)	75	11 (14.7)	(7.6, 24.7)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	74	3 (4.1)	(0.8, 11.4)	75	1 (1.3)	(0.0, 7.2)
	Grade 4	74	0	(0.0, 4.9)	75	0	(0.0, 4.8)
	Headache[e]						
	Any	73	25 (34.2)	(23.5, 46.3)	74	23 (31.1)	(20.8, 42.9)
	Mild	73	13 (17.8)	(9.8, 28.5)	74	13 (17.6)	(9.7, 28.2)
	Moderate	73	10 (13.7)	(6.8, 23.8)	74	9 (12.2)	(5.7, 21.8)
	Severe	73	2 (2.7)	(0.3, 9.5)	74	1 (1.4)	(0.0, 7.3)
	Grade 4	73	0	(0.0, 4.9)	74	0	(0.0, 4.9)
	Chills[e]						
	Any	73	19 (26.0)	(16.5, 37.6)	74	9 (12.2)	(5.7, 21.8)
	Mild	73	8 (11.0)	(4.9, 20.5)	74	7 (9.5)	(3.9, 18.5)
	Moderate	73	9 (12.3)	(5.8, 22.1)	74	2 (2.7)	(0.3, 9.4)
	Severe	73	2 (2.7)	(0.3, 9.5)	74	0	(0.0, 4.9)
	Grade 4	73	0	(0.0, 4.9)	74	0	(0.0, 4.9)
	Vomiting[f]						
	Any	72	3 (4.2)	(0.9, 11.7)	74	3 (4.1)	(0.8, 11.4)
	Mild	72	2 (2.8)	(0.3, 9.7)	74	1 (1.4)	(0.0, 7.3)
	Moderate	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	Severe	72	1 (1.4)	(0.0, 7.5)	74	2 (2.7)	(0.3, 9.4)
	Grade 4	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	Diarrhea[g]						
	Any	72	8 (11.1)	(4.9, 20.7)	74	15 (20.3)	(11.8, 31.2)
	Mild	72	5 (6.9)	(2.3, 15.5)	74	10 (13.5)	(6.7, 23.5)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	72	2 (2.8)	(0.3, 9.7)	74	4 (5.4)	(1.5, 13.3)
	Severe	72	1 (1.4)	(0.0, 7.5)	74	1 (1.4)	(0.0, 7.3)
	Grade 4	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)
	New or worsened muscle pain[e]						
	Any	73	19 (26.0)	(16.5, 37.6)	74	14 (18.9)	(10.7, 29.7)
	Mild	73	13 (17.8)	(9.8, 28.5)	74	8 (10.8)	(4.8, 20.2)
	Moderate	73	5 (6.8)	(2.3, 15.3)	74	6 (8.1)	(3.0, 16.8)
	Severe	73	1 (1.4)	(0.0, 7.4)	74	0	(0.0, 4.9)
	Grade 4	73	0	(0.0, 4.9)	74	0	(0.0, 4.9)
	New or worsened joint pain[e]						
	Any	73	14 (19.2)	(10.9, 30.1)	74	11 (14.9)	(7.7, 25.0)
	Mild	73	8 (11.0)	(4.9, 20.5)	74	5 (6.8)	(2.2, 15.1)
	Moderate	73	6 (8.2)	(3.1, 17.0)	74	6 (8.1)	(3.0, 16.8)
	Severe	73	0	(0.0, 4.9)	74	0	(0.0, 4.9)
	Grade 4	73	0	(0.0, 4.9)	74	0	(0.0, 4.9)
	Any systemic event[h]	74	52 (70.3)	(58.5, 80.3)	75	40 (53.3)	(41.4, 64.9)
	Use of antipyretic or pain medication[i]	72	20 (27.8)	(17.9, 39.6)	74	12 (16.2)	(8.7, 26.6)

Abbreviation: HIV = human immunodeficiency virus.

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

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

related 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 (22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:24)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 sBLA CBER EDIARY/adce s020 se hiv p3 saf

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Positive	1	Fever						
		Any	177	22 (12.4)	(8.0, 18.2)	187	4 (2.1)	(0.6, 5.4)
		≥38.0°C to 38.4°C	177	17 (9.6)	(5.7, 14.9)	187	1 (0.5)	(0.0, 2.9)
		>38.4°C to 38.9°C	177	4 (2.3)	(0.6, 5.7)	187	1 (0.5)	(0.0, 2.9)
		>38.9°C to 40.0°C	177	1 (0.6)	(0.0, 3.1)	187	2 (1.1)	(0.1, 3.8)
		>40.0°C	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Unknown[d]	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Fatigue[e]						
		Any	177	80 (45.2)	(37.7, 52.8)	187	35 (18.7)	(13.4, 25.1)
		Mild	177	32 (18.1)	(12.7, 24.6)	187	20 (10.7)	(6.7, 16.0)
		Moderate	177	47 (26.6)	(20.2, 33.7)	187	15 (8.0)	(4.6, 12.9)
		Severe	177	1 (0.6)	(0.0, 3.1)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Headache[e]						
		Any	177	70 (39.5)	(32.3, 47.2)	187	43 (23.0)	(17.2, 29.7)
		Mild	177	36 (20.3)	(14.7, 27.0)	187	31 (16.6)	(11.6, 22.7)
		Moderate	177	31 (17.5)	(12.2, 23.9)	187	9 (4.8)	(2.2, 8.9)
		Severe	177	3 (1.7)	(0.4, 4.9)	187	3 (1.6)	(0.3, 4.6)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Chills[e]						
		Any	177	49 (27.7)	(21.2, 34.9)	187	8 (4.3)	(1.9, 8.3)
		Mild	177	33 (18.6)	(13.2, 25.2)	187	5 (2.7)	(0.9, 6.1)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Moderate	177	14 (7.9)	(4.4, 12.9)	187	3 (1.6)	(0.3, 4.6)
		Severe	177	2 (1.1)	(0.1, 4.0)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Vomiting[f]						
		Any	177	4 (2.3)	(0.6, 5.7)	187	3 (1.6)	(0.3, 4.6)
		Mild	177	3 (1.7)	(0.4, 4.9)	187	3 (1.6)	(0.3, 4.6)
		Moderate	177	1 (0.6)	(0.0, 3.1)	187	0	(0.0, 2.0)
		Severe	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Diarrhea[g]						
		Any	177	10 (5.6)	(2.7, 10.1)	187	13 (7.0)	(3.8, 11.6)
		Mild	177	9 (5.1)	(2.4, 9.4)	187	10 (5.3)	(2.6, 9.6)
		Moderate	177	1 (0.6)	(0.0, 3.1)	187	3 (1.6)	(0.3, 4.6)
		Severe	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		New or worsened muscle pain[e]						
		Any	177	55 (31.1)	(24.3, 38.5)	187	20 (10.7)	(6.7, 16.0)
		Mild	177	18 (10.2)	(6.1, 15.6)	187	13 (7.0)	(3.8, 11.6)
		Moderate	177	35 (19.8)	(14.2, 26.4)	187	7 (3.7)	(1.5, 7.6)
		Severe	177	2 (1.1)	(0.1, 4.0)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		New or worsened joint pain[e]						

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	177	33 (18.6)	(13.2, 25.2)	187	10 (5.3)	(2.6, 9.6)
		Mild	177	20 (11.3)	(7.0, 16.9)	187	5 (2.7)	(0.9, 6.1)
		Moderate	177	12 (6.8)	(3.6, 11.5)	187	5 (2.7)	(0.9, 6.1)
		Severe	177	1 (0.6)	(0.0, 3.1)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Any systemic event[h]	177	115 (65.0)	(57.5, 72.0)	187	77 (41.2)	(34.0, 48.6)
		Use of antipyretic or pain medication[i]	177	67 (37.9)	(30.7, 45.4)	187	28 (15.0)	(10.2, 20.9)
	2	Fever						
		Any	153	12 (7.8)	(4.1, 13.3)	165	1 (0.6)	(0.0, 3.3)
		≥38.0°C to 38.4°C	153	11 (7.2)	(3.6, 12.5)	165	0	(0.0, 2.2)
		>38.4°C to 38.9°C	153	1 (0.7)	(0.0, 3.6)	165	1 (0.6)	(0.0, 3.3)
		>38.9°C to 40.0°C	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		>40.0°C	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Unknown[d]	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Fatigue[e]						
		Any	153	56 (36.6)	(29.0, 44.8)	165	27 (16.4)	(11.1, 22.9)
		Mild	153	23 (15.0)	(9.8, 21.7)	165	11 (6.7)	(3.4, 11.6)
		Moderate	153	29 (19.0)	(13.1, 26.1)	165	15 (9.1)	(5.2, 14.6)
		Severe	153	4 (2.6)	(0.7, 6.6)	165	1 (0.6)	(0.0, 3.3)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Headache[e]						

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	153	54 (35.3)	(27.7, 43.4)	165	32 (19.4)	(13.7, 26.3)
		Mild	153	29 (19.0)	(13.1, 26.1)	165	18 (10.9)	(6.6, 16.7)
		Moderate	153	22 (14.4)	(9.2, 21.0)	165	11 (6.7)	(3.4, 11.6)
		Severe	153	3 (2.0)	(0.4, 5.6)	165	3 (1.8)	(0.4, 5.2)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Chills[e]						
		Any	153	29 (19.0)	(13.1, 26.1)	165	2 (1.2)	(0.1, 4.3)
		Mild	153	15 (9.8)	(5.6, 15.7)	165	2 (1.2)	(0.1, 4.3)
		Moderate	153	14 (9.2)	(5.1, 14.9)	165	0	(0.0, 2.2)
		Severe	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Vomiting[f]						
		Any	153	2 (1.3)	(0.2, 4.6)	165	4 (2.4)	(0.7, 6.1)
		Mild	153	1 (0.7)	(0.0, 3.6)	165	2 (1.2)	(0.1, 4.3)
		Moderate	153	0	(0.0, 2.4)	165	2 (1.2)	(0.1, 4.3)
		Severe	153	1 (0.7)	(0.0, 3.6)	165	0	(0.0, 2.2)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Diarrhea[g]						
		Any	153	10 (6.5)	(3.2, 11.7)	165	16 (9.7)	(5.6, 15.3)
		Mild	153	6 (3.9)	(1.5, 8.3)	165	10 (6.1)	(2.9, 10.9)
		Moderate	153	4 (2.6)	(0.7, 6.6)	165	4 (2.4)	(0.7, 6.1)
		Severe	153	0	(0.0, 2.4)	165	2 (1.2)	(0.1, 4.3)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	**Dose**	**Systemic Event**	**N[a]**	**n[b] (%)**	**(95% CI[c])**	**N[a]**	**n[b] (%)**	**(95% CI[c])**
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		New or worsened muscle pain[e]						
		Any	153	42 (27.5)	(20.6, 35.2)	165	14 (8.5)	(4.7, 13.8)
		Mild	153	16 (10.5)	(6.1, 16.4)	165	7 (4.2)	(1.7, 8.5)
		Moderate	153	21 (13.7)	(8.7, 20.2)	165	7 (4.2)	(1.7, 8.5)
		Severe	153	5 (3.3)	(1.1, 7.5)	165	0	(0.0, 2.2)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		New or worsened joint pain[e]						
		Any	153	27 (17.6)	(12.0, 24.6)	165	9 (5.5)	(2.5, 10.1)
		Mild	153	12 (7.8)	(4.1, 13.3)	165	7 (4.2)	(1.7, 8.5)
		Moderate	153	15 (9.8)	(5.6, 15.7)	165	2 (1.2)	(0.1, 4.3)
		Severe	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Any systemic event[h]	153	87 (56.9)	(48.6, 64.8)	165	50 (30.3)	(23.4, 37.9)
		Use of antipyretic or pain medication[i]	153	48 (31.4)	(24.1, 39.4)	165	16 (9.7)	(5.6, 15.3)
	Any dose	Fever						
		Any	177	31 (17.5)	(12.2, 23.9)	187	5 (2.7)	(0.9, 6.1)
		≥38.0°C to 38.4°C	177	25 (14.1)	(9.4, 20.1)	187	1 (0.5)	(0.0, 2.9)
		>38.4°C to 38.9°C	177	5 (2.8)	(0.9, 6.5)	187	2 (1.1)	(0.1, 3.8)
		>38.9°C to 40.0°C	177	1 (0.6)	(0.0, 3.1)	187	2 (1.1)	(0.1, 3.8)
		>40.0°C	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Unknown[d]	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Fatigue[e]						
		Any	177	96 (54.2)	(46.6, 61.7)	187	50 (26.7)	(20.5, 33.7)
		Mild	177	33 (18.6)	(13.2, 25.2)	187	24 (12.8)	(8.4, 18.5)
		Moderate	177	59 (33.3)	(26.4, 40.8)	187	25 (13.4)	(8.8, 19.1)
		Severe	177	4 (2.3)	(0.6, 5.7)	187	1 (0.5)	(0.0, 2.9)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Headache[e]						
		Any	177	88 (49.7)	(42.1, 57.3)	187	59 (31.6)	(25.0, 38.7)
		Mild	177	39 (22.0)	(16.2, 28.9)	187	35 (18.7)	(13.4, 25.1)
		Moderate	177	43 (24.3)	(18.2, 31.3)	187	18 (9.6)	(5.8, 14.8)
		Severe	177	6 (3.4)	(1.3, 7.2)	187	6 (3.2)	(1.2, 6.9)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Chills[e]						
		Any	177	58 (32.8)	(25.9, 40.2)	187	10 (5.3)	(2.6, 9.6)
		Mild	177	34 (19.2)	(13.7, 25.8)	187	7 (3.7)	(1.5, 7.6)
		Moderate	177	22 (12.4)	(8.0, 18.2)	187	3 (1.6)	(0.3, 4.6)
		Severe	177	2 (1.1)	(0.1, 4.0)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Vomiting[f]						
		Any	177	6 (3.4)	(1.3, 7.2)	187	6 (3.2)	(1.2, 6.9)
		Mild	177	4 (2.3)	(0.6, 5.7)	187	4 (2.1)	(0.6, 5.4)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Moderate	177	1 (0.6)	(0.0, 3.1)	187	2 (1.1)	(0.1, 3.8)
		Severe	177	1 (0.6)	(0.0, 3.1)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Diarrhea[g]						
		Any	177	18 (10.2)	(6.1, 15.6)	187	27 (14.4)	(9.7, 20.3)
		Mild	177	13 (7.3)	(4.0, 12.2)	187	18 (9.6)	(5.8, 14.8)
		Moderate	177	5 (2.8)	(0.9, 6.5)	187	7 (3.7)	(1.5, 7.6)
		Severe	177	0	(0.0, 2.1)	187	2 (1.1)	(0.1, 3.8)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		New or worsened muscle pain[e]						
		Any	177	71 (40.1)	(32.8, 47.7)	187	30 (16.0)	(11.1, 22.1)
		Mild	177	23 (13.0)	(8.4, 18.9)	187	16 (8.6)	(5.0, 13.5)
		Moderate	177	42 (23.7)	(17.7, 30.7)	187	14 (7.5)	(4.2, 12.2)
		Severe	177	6 (3.4)	(1.3, 7.2)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		New or worsened joint pain[e]						
		Any	177	48 (27.1)	(20.7, 34.3)	187	19 (10.2)	(6.2, 15.4)
		Mild	177	25 (14.1)	(9.4, 20.1)	187	12 (6.4)	(3.4, 10.9)
		Moderate	177	22 (12.4)	(8.0, 18.2)	187	7 (3.7)	(1.5, 7.6)
		Severe	177	1 (0.6)	(0.0, 3.1)	187	0	(0.0, 2.0)
		Grade 4	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Any systemic event[h]	177	129 (72.9)	(65.7, 79.3)	187	96 (51.3)	(43.9, 58.7)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Use of antipyretic or pain medication[i]	177	77 (43.5)	(36.1, 51.1)	187	38 (20.3)	(14.8, 26.8)
Negative	1	Fever						
		Any	4701	123 (2.6)	(2.2, 3.1)	4690	30 (0.6)	(0.4, 0.9)
		≥38.0°C to 38.4°C	4701	92 (2.0)	(1.6, 2.4)	4690	18 (0.4)	(0.2, 0.6)
		>38.4°C to 38.9°C	4701	22 (0.5)	(0.3, 0.7)	4690	7 (0.1)	(0.1, 0.3)
		>38.9°C to 40.0°C	4701	7 (0.1)	(0.1, 0.3)	4690	4 (0.1)	(0.0, 0.2)
		>40.0°C	4701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Unknown[d]	4701	2 (0.0)	(0.0, 0.2)	4690	1 (0.0)	(0.0, 0.1)
		Fatigue[e]						
		Any	4702	2013 (42.8)	(41.4, 44.2)	4690	1368 (29.2)	(27.9, 30.5)
		Mild	4702	1140 (24.2)	(23.0, 25.5)	4690	829 (17.7)	(16.6, 18.8)
		Moderate	4702	832 (17.7)	(16.6, 18.8)	4690	519 (11.1)	(10.2, 12.0)
		Severe	4702	41 (0.9)	(0.6, 1.2)	4690	20 (0.4)	(0.3, 0.7)
		Grade 4	4702	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Headache[e]						
		Any	4703	1682 (35.8)	(34.4, 37.2)	4692	1294 (27.6)	(26.3, 28.9)
		Mild	4703	1124 (23.9)	(22.7, 25.1)	4692	867 (18.5)	(17.4, 19.6)
		Moderate	4703	527 (11.2)	(10.3, 12.1)	4692	403 (8.6)	(7.8, 9.4)
		Severe	4703	31 (0.7)	(0.4, 0.9)	4692	24 (0.5)	(0.3, 0.8)
		Grade 4	4703	0	(0.0, 0.1)	4692	0	(0.0, 0.1)
		Chills[e]						

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	4702	552 (11.7)	(10.8, 12.7)	4690	260 (5.5)	(4.9, 6.2)
		Mild	4702	402 (8.5)	(7.8, 9.4)	4690	192 (4.1)	(3.5, 4.7)
		Moderate	4702	138 (2.9)	(2.5, 3.5)	4690	65 (1.4)	(1.1, 1.8)
		Severe	4702	12 (0.3)	(0.1, 0.4)	4690	3 (0.1)	(0.0, 0.2)
		Grade 4	4702	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Vomiting[f]						
		Any	4701	39 (0.8)	(0.6, 1.1)	4690	41 (0.9)	(0.6, 1.2)
		Mild	4701	35 (0.7)	(0.5, 1.0)	4690	35 (0.7)	(0.5, 1.0)
		Moderate	4701	4 (0.1)	(0.0, 0.2)	4690	5 (0.1)	(0.0, 0.2)
		Severe	4701	0	(0.0, 0.1)	4690	1 (0.0)	(0.0, 0.1)
		Grade 4	4701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Diarrhea[g]						
		Any	4701	462 (9.8)	(9.0, 10.7)	4691	441 (9.4)	(8.6, 10.3)
		Mild	4701	375 (8.0)	(7.2, 8.8)	4691	364 (7.8)	(7.0, 8.6)
		Moderate	4701	80 (1.7)	(1.4, 2.1)	4691	75 (1.6)	(1.3, 2.0)
		Severe	4701	7 (0.1)	(0.1, 0.3)	4691	2 (0.0)	(0.0, 0.2)
		Grade 4	4701	0	(0.0, 0.1)	4691	0	(0.0, 0.1)
		New or worsened muscle pain[e]						
		Any	4702	878 (18.7)	(17.6, 19.8)	4690	471 (10.0)	(9.2, 10.9)
		Mild	4702	517 (11.0)	(10.1, 11.9)	4690	327 (7.0)	(6.3, 7.7)
		Moderate	4702	348 (7.4)	(6.7, 8.2)	4690	139 (3.0)	(2.5, 3.5)
		Severe	4702	13 (0.3)	(0.1, 0.5)	4690	5 (0.1)	(0.0, 0.2)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Grade 4	4702	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		New or worsened joint pain[e]						
		Any	4701	480 (10.2)	(9.4, 11.1)	4690	282 (6.0)	(5.3, 6.7)
		Mild	4701	298 (6.3)	(5.7, 7.1)	4690	185 (3.9)	(3.4, 4.5)
		Moderate	4701	176 (3.7)	(3.2, 4.3)	4690	95 (2.0)	(1.6, 2.5)
		Severe	4701	6 (0.1)	(0.0, 0.3)	4690	2 (0.0)	(0.0, 0.2)
		Grade 4	4701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Any systemic event[h]	4703	2830 (60.2)	(58.8, 61.6)	4692	2226 (47.4)	(46.0, 48.9)
		Use of antipyretic or pain medication[i]	4701	1109 (23.6)	(22.4, 24.8)	4690	592 (12.6)	(11.7, 13.6)
	2	Fever						
		Any	4379	666 (15.2)	(14.2, 16.3)	4335	15 (0.3)	(0.2, 0.6)
		≥38.0°C to 38.4°C	4379	399 (9.1)	(8.3, 10.0)	4335	7 (0.2)	(0.1, 0.3)
		>38.4°C to 38.9°C	4379	199 (4.5)	(3.9, 5.2)	4335	3 (0.1)	(0.0, 0.2)
		>38.9°C to 40.0°C	4379	46 (1.1)	(0.8, 1.4)	4335	3 (0.1)	(0.0, 0.2)
		>40.0°C	4379	1 (0.0)	(0.0, 0.1)	4335	0	(0.0, 0.1)
		Unknown[d]	4379	21 (0.5)	(0.3, 0.7)	4335	2 (0.0)	(0.0, 0.2)
		Fatigue[e]						
		Any	4378	2545 (58.1)	(56.7, 59.6)	4335	893 (20.6)	(19.4, 21.8)
		Mild	4378	930 (21.2)	(20.0, 22.5)	4335	493 (11.4)	(10.4, 12.4)
		Moderate	4378	1415 (32.3)	(30.9, 33.7)	4335	385 (8.9)	(8.1, 9.8)
		Severe	4378	199 (4.5)	(3.9, 5.2)	4335	15 (0.3)	(0.2, 0.6)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Grade 4	4378	1 (0.0)	(0.0, 0.1)	4335	0	(0.0, 0.1)
		Headache[e]						
		Any	4381	2135 (48.7)	(47.2, 50.2)	4336	880 (20.3)	(19.1, 21.5)
		Mild	4381	1139 (26.0)	(24.7, 27.3)	4336	579 (13.4)	(12.4, 14.4)
		Moderate	4381	896 (20.5)	(19.3, 21.7)	4336	281 (6.5)	(5.8, 7.3)
		Severe	4381	100 (2.3)	(1.9, 2.8)	4336	20 (0.5)	(0.3, 0.7)
		Grade 4	4381	0	(0.0, 0.1)	4336	0	(0.0, 0.1)
		Chills[e]						
		Any	4378	1431 (32.7)	(31.3, 34.1)	4334	169 (3.9)	(3.3, 4.5)
		Mild	4378	699 (16.0)	(14.9, 17.1)	4334	133 (3.1)	(2.6, 3.6)
		Moderate	4378	642 (14.7)	(13.6, 15.7)	4334	34 (0.8)	(0.5, 1.1)
		Severe	4378	90 (2.1)	(1.7, 2.5)	4334	2 (0.0)	(0.0, 0.2)
		Grade 4	4378	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Vomiting[f]						
		Any	4368	69 (1.6)	(1.2, 2.0)	4334	31 (0.7)	(0.5, 1.0)
		Mild	4368	51 (1.2)	(0.9, 1.5)	4334	23 (0.5)	(0.3, 0.8)
		Moderate	4368	13 (0.3)	(0.2, 0.5)	4334	8 (0.2)	(0.1, 0.4)
		Severe	4368	5 (0.1)	(0.0, 0.3)	4334	0	(0.0, 0.1)
		Grade 4	4368	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Diarrhea[g]						
		Any	4368	412 (9.4)	(8.6, 10.3)	4336	291 (6.7)	(6.0, 7.5)
		Mild	4368	338 (7.7)	(7.0, 8.6)	4336	235 (5.4)	(4.8, 6.1)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Moderate	4368	66 (1.5)	(1.2, 1.9)	4336	53 (1.2)	(0.9, 1.6)
		Severe	4368	8 (0.2)	(0.1, 0.4)	4336	3 (0.1)	(0.0, 0.2)
		Grade 4	4368	0	(0.0, 0.1)	4336	0	(0.0, 0.1)
		New or worsened muscle pain[e]						
		Any	4381	1565 (35.7)	(34.3, 37.2)	4334	319 (7.4)	(6.6, 8.2)
		Mild	4381	663 (15.1)	(14.1, 16.2)	4334	206 (4.8)	(4.1, 5.4)
		Moderate	4381	825 (18.8)	(17.7, 20.0)	4334	109 (2.5)	(2.1, 3.0)
		Severe	4381	77 (1.8)	(1.4, 2.2)	4334	4 (0.1)	(0.0, 0.2)
		Grade 4	4381	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		New or worsened joint pain[e]						
		Any	4371	969 (22.2)	(20.9, 23.4)	4334	209 (4.8)	(4.2, 5.5)
		Mild	4371	464 (10.6)	(9.7, 11.6)	4334	118 (2.7)	(2.3, 3.3)
		Moderate	4371	469 (10.7)	(9.8, 11.7)	4334	86 (2.0)	(1.6, 2.4)
		Severe	4371	36 (0.8)	(0.6, 1.1)	4334	5 (0.1)	(0.0, 0.3)
		Grade 4	4371	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Any systemic event[h]	4396	3171 (72.1)	(70.8, 73.5)	4339	1493 (34.4)	(33.0, 35.8)
		Use of antipyretic or pain medication[i]	4368	1845 (42.2)	(40.8, 43.7)	4334	470 (10.8)	(9.9, 11.8)
	Any dose	Fever						
		Any	4718	736 (15.6)	(14.6, 16.7)	4709	42 (0.9)	(0.6, 1.2)
		≥38.0°C to 38.4°C	4718	451 (9.6)	(8.7, 10.4)	4709	24 (0.5)	(0.3, 0.8)
		>38.4°C to 38.9°C	4718	213 (4.5)	(3.9, 5.1)	4709	9 (0.2)	(0.1, 0.4)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		>38.9°C to 40.0°C	4718	49 (1.0)	(0.8, 1.4)	4709	6 (0.1)	(0.0, 0.3)
		>40.0°C	4718	1 (0.0)	(0.0, 0.1)	4709	0	(0.0, 0.1)
		Unknown[d]	4718	22 (0.5)	(0.3, 0.7)	4709	3 (0.1)	(0.0, 0.2)
		Fatigue[e]						
		Any	4718	3074 (65.2)	(63.8, 66.5)	4708	1702 (36.2)	(34.8, 37.5)
		Mild	4718	1119 (23.7)	(22.5, 25.0)	4708	931 (19.8)	(18.6, 20.9)
		Moderate	4718	1721 (36.5)	(35.1, 37.9)	4708	740 (15.7)	(14.7, 16.8)
		Severe	4718	233 (4.9)	(4.3, 5.6)	4708	31 (0.7)	(0.4, 0.9)
		Grade 4	4718	1 (0.0)	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Headache[e]						
		Any	4718	2718 (57.6)	(56.2, 59.0)	4710	1656 (35.2)	(33.8, 36.5)
		Mild	4718	1414 (30.0)	(28.7, 31.3)	4710	1040 (22.1)	(20.9, 23.3)
		Moderate	4718	1179 (25.0)	(23.8, 26.3)	4710	573 (12.2)	(11.2, 13.1)
		Severe	4718	125 (2.6)	(2.2, 3.1)	4710	43 (0.9)	(0.7, 1.2)
		Grade 4	4718	0	(0.0, 0.1)	4710	0	(0.0, 0.1)
		Chills[e]						
		Any	4718	1651 (35.0)	(33.6, 36.4)	4708	370 (7.9)	(7.1, 8.7)
		Mild	4718	841 (17.8)	(16.7, 18.9)	4708	279 (5.9)	(5.3, 6.6)
		Moderate	4718	710 (15.0)	(14.0, 16.1)	4708	86 (1.8)	(1.5, 2.3)
		Severe	4718	100 (2.1)	(1.7, 2.6)	4708	5 (0.1)	(0.0, 0.2)
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Vomiting[f]						

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Any	4718	103 (2.2)	(1.8, 2.6)	4708	67 (1.4)	(1.1, 1.8)
		Mild	4718	82 (1.7)	(1.4, 2.2)	4708	53 (1.1)	(0.8, 1.5)
		Moderate	4718	16 (0.3)	(0.2, 0.6)	4708	13 (0.3)	(0.1, 0.5)
		Severe	4718	5 (0.1)	(0.0, 0.2)	4708	1 (0.0)	(0.0, 0.1)
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Diarrhea[g]						
		Any	4718	737 (15.6)	(14.6, 16.7)	4709	633 (13.4)	(12.5, 14.4)
		Mild	4718	587 (12.4)	(11.5, 13.4)	4709	507 (10.8)	(9.9, 11.7)
		Moderate	4718	135 (2.9)	(2.4, 3.4)	4709	121 (2.6)	(2.1, 3.1)
		Severe	4718	15 (0.3)	(0.2, 0.5)	4709	5 (0.1)	(0.0, 0.2)
		Grade 4	4718	0	(0.0, 0.1)	4709	0	(0.0, 0.1)
		New or worsened muscle pain[e]						
		Any	4718	1913 (40.5)	(39.1, 42.0)	4708	658 (14.0)	(13.0, 15.0)
		Mild	4718	806 (17.1)	(16.0, 18.2)	4708	423 (9.0)	(8.2, 9.8)
		Moderate	4718	1019 (21.6)	(20.4, 22.8)	4708	226 (4.8)	(4.2, 5.5)
		Severe	4718	88 (1.9)	(1.5, 2.3)	4708	9 (0.2)	(0.1, 0.4)
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		New or worsened joint pain[e]						
		Any	4718	1186 (25.1)	(23.9, 26.4)	4708	422 (9.0)	(8.2, 9.8)
		Mild	4718	563 (11.9)	(11.0, 12.9)	4708	246 (5.2)	(4.6, 5.9)
		Moderate	4718	581 (12.3)	(11.4, 13.3)	4708	169 (3.6)	(3.1, 4.2)
		Severe	4718	42 (0.9)	(0.6, 1.2)	4708	7 (0.1)	(0.1, 0.3)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Any systemic event[h]	4718	3734 (79.1)	(78.0, 80.3)	4710	2613 (55.5)	(54.0, 56.9)
		Use of antipyretic or pain medication[i]	4718	2209 (46.8)	(45.4, 48.3)	4708	881 (18.7)	(17.6, 19.9)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
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 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 (22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:24)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_CBER_EDIARY/adce_s020_se_base_p3_saf

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
16-55 Years	1	Fever						
		Any	2899	120 (4.1)	(3.4, 4.9)	2908	25 (0.9)	(0.6, 1.3)
		≥38.0°C to 38.4°C	2899	86 (3.0)	(2.4, 3.7)	2908	16 (0.6)	(0.3, 0.9)
		>38.4°C to 38.9°C	2899	25 (0.9)	(0.6, 1.3)	2908	5 (0.2)	(0.1, 0.4)
		>38.9°C to 40.0°C	2899	8 (0.3)	(0.1, 0.5)	2908	4 (0.1)	(0.0, 0.4)
		>40.0°C	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Unknown[d]	2899	1 (0.0)	(0.0, 0.2)	2908	0	(0.0, 0.1)
		Fatigue[e]						
		Any	2900	1433 (49.4)	(47.6, 51.3)	2908	960 (33.0)	(31.3, 34.8)
		Mild	2900	762 (26.3)	(24.7, 27.9)	2908	570 (19.6)	(18.2, 21.1)
		Moderate	2900	630 (21.7)	(20.2, 23.3)	2908	372 (12.8)	(11.6, 14.1)
		Severe	2900	41 (1.4)	(1.0, 1.9)	2908	18 (0.6)	(0.4, 1.0)
		Grade 4	2900	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Headache[e]						
		Any	2901	1264 (43.6)	(41.8, 45.4)	2909	976 (33.6)	(31.8, 35.3)
		Mild	2901	787 (27.1)	(25.5, 28.8)	2909	633 (21.8)	(20.3, 23.3)
		Moderate	2901	444 (15.3)	(14.0, 16.7)	2909	319 (11.0)	(9.9, 12.2)
		Severe	2901	33 (1.1)	(0.8, 1.6)	2909	24 (0.8)	(0.5, 1.2)
		Grade 4	2901	0	(0.0, 0.1)	2909	0	(0.0, 0.1)
		Chills[e]						
		Any	2900	481 (16.6)	(15.2, 18.0)	2908	200 (6.9)	(6.0, 7.9)
		Mild	2900	338 (11.7)	(10.5, 12.9)	2908	149 (5.1)	(4.4, 6.0)
		Moderate	2900	128 (4.4)	(3.7, 5.2)	2908	49 (1.7)	(1.2, 2.2)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Severe	2900	15 (0.5)	(0.3, 0.9)	2908	2 (0.1)	(0.0, 0.2)
		Grade 4	2900	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Vomiting[f]						
		Any	2899	34 (1.2)	(0.8, 1.6)	2908	36 (1.2)	(0.9, 1.7)
		Mild	2899	29 (1.0)	(0.7, 1.4)	2908	30 (1.0)	(0.7, 1.5)
		Moderate	2899	5 (0.2)	(0.1, 0.4)	2908	5 (0.2)	(0.1, 0.4)
		Severe	2899	0	(0.0, 0.1)	2908	1 (0.0)	(0.0, 0.2)
		Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Diarrhea[g]						
		Any	2899	309 (10.7)	(9.6, 11.8)	2908	324 (11.1)	(10.0, 12.3)
		Mild	2899	251 (8.7)	(7.7, 9.7)	2908	265 (9.1)	(8.1, 10.2)
		Moderate	2899	55 (1.9)	(1.4, 2.5)	2908	58 (2.0)	(1.5, 2.6)
		Severe	2899	3 (0.1)	(0.0, 0.3)	2908	1 (0.0)	(0.0, 0.2)
		Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		New or worsened muscle pain[e]						
		Any	2900	667 (23.0)	(21.5, 24.6)	2908	329 (11.3)	(10.2, 12.5)
		Mild	2900	355 (12.2)	(11.1, 13.5)	2908	231 (7.9)	(7.0, 9.0)
		Moderate	2900	297 (10.2)	(9.2, 11.4)	2908	96 (3.3)	(2.7, 4.0)
		Severe	2900	15 (0.5)	(0.3, 0.9)	2908	2 (0.1)	(0.0, 0.2)
		Grade 4	2900	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		New or worsened joint pain[e]						
		Any	2899	342 (11.8)	(10.6, 13.0)	2908	168 (5.8)	(5.0, 6.7)
		Mild	2899	200 (6.9)	(6.0, 7.9)	2908	112 (3.9)	(3.2, 4.6)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Moderate	2899	137 (4.7)	(4.0, 5.6)	2908	55 (1.9)	(1.4, 2.5)
		Severe	2899	5 (0.2)	(0.1, 0.4)	2908	1 (0.0)	(0.0, 0.2)
		Grade 4	2899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Any systemic event[h]	2901	1983 (68.4)	(66.6, 70.0)	2909	1560 (53.6)	(51.8, 55.5)
		Use of antipyretic or pain medication[i]	2899	805 (27.8)	(26.1, 29.4)	2908	398 (13.7)	(12.5, 15.0)
	2	Fever						
		Any	2691	456 (16.9)	(15.5, 18.4)	2685	13 (0.5)	(0.3, 0.8)
		≥38.0°C to 38.4°C	2691	254 (9.4)	(8.4, 10.6)	2685	5 (0.2)	(0.1, 0.4)
		>38.4°C to 38.9°C	2691	146 (5.4)	(4.6, 6.3)	2685	4 (0.1)	(0.0, 0.4)
		>38.9°C to 40.0°C	2691	39 (1.4)	(1.0, 2.0)	2685	2 (0.1)	(0.0, 0.3)
		>40.0°C	2691	1 (0.0)	(0.0, 0.2)	2685	0	(0.0, 0.1)
		Unknown[d]	2691	16 (0.6)	(0.3, 1.0)	2685	2 (0.1)	(0.0, 0.3)
		Fatigue[e]						
		Any	2690	1659 (61.7)	(59.8, 63.5)	2684	617 (23.0)	(21.4, 24.6)
		Mild	2690	563 (20.9)	(19.4, 22.5)	2684	320 (11.9)	(10.7, 13.2)
		Moderate	2690	952 (35.4)	(33.6, 37.2)	2684	283 (10.5)	(9.4, 11.8)
		Severe	2690	144 (5.4)	(4.5, 6.3)	2684	14 (0.5)	(0.3, 0.9)
		Grade 4	2690	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Headache[e]						
		Any	2688	1456 (54.2)	(52.3, 56.1)	2686	657 (24.5)	(22.8, 26.1)
		Mild	2688	704 (26.2)	(24.5, 27.9)	2686	409 (15.2)	(13.9, 16.6)
		Moderate	2688	660 (24.6)	(22.9, 26.2)	2686	230 (8.6)	(7.5, 9.7)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Severe	2688	92 (3.4)	(2.8, 4.2)	2686	18 (0.7)	(0.4, 1.1)
		Grade 4	2688	0	(0.0, 0.1)	2686	0	(0.0, 0.1)
		Chills[e]						
		Any	2688	1024 (38.1)	(36.3, 40.0)	2684	115 (4.3)	(3.6, 5.1)
		Mild	2688	482 (17.9)	(16.5, 19.4)	2684	90 (3.4)	(2.7, 4.1)
		Moderate	2688	473 (17.6)	(16.2, 19.1)	2684	23 (0.9)	(0.5, 1.3)
		Severe	2688	69 (2.6)	(2.0, 3.2)	2684	2 (0.1)	(0.0, 0.3)
		Grade 4	2688	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Vomiting[f]						
		Any	2682	58 (2.2)	(1.6, 2.8)	2684	30 (1.1)	(0.8, 1.6)
		Mild	2682	42 (1.6)	(1.1, 2.1)	2684	20 (0.7)	(0.5, 1.1)
		Moderate	2682	12 (0.4)	(0.2, 0.8)	2684	10 (0.4)	(0.2, 0.7)
		Severe	2682	4 (0.1)	(0.0, 0.4)	2684	0	(0.0, 0.1)
		Grade 4	2682	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Diarrhea[g]						
		Any	2682	269 (10.0)	(8.9, 11.2)	2685	206 (7.7)	(6.7, 8.7)
		Mild	2682	219 (8.2)	(7.2, 9.3)	2685	170 (6.3)	(5.4, 7.3)
		Moderate	2682	44 (1.6)	(1.2, 2.2)	2685	35 (1.3)	(0.9, 1.8)
		Severe	2682	6 (0.2)	(0.1, 0.5)	2685	1 (0.0)	(0.0, 0.2)
		Grade 4	2682	0	(0.0, 0.1)	2685	0	(0.0, 0.1)
		New or worsened muscle pain[e]						
		Any	2692	1069 (39.7)	(37.9, 41.6)	2684	237 (8.8)	(7.8, 10.0)
		Mild	2692	450 (16.7)	(15.3, 18.2)	2684	150 (5.6)	(4.7, 6.5)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Moderate	2692	557 (20.7)	(19.2, 22.3)	2684	84 (3.1)	(2.5, 3.9)
		Severe	2692	62 (2.3)	(1.8, 2.9)	2684	3 (0.1)	(0.0, 0.3)
		Grade 4	2692	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		New or worsened joint pain[e]						
		Any	2684	643 (24.0)	(22.4, 25.6)	2684	147 (5.5)	(4.6, 6.4)
		Mild	2684	293 (10.9)	(9.8, 12.2)	2684	82 (3.1)	(2.4, 3.8)
		Moderate	2684	323 (12.0)	(10.8, 13.3)	2684	61 (2.3)	(1.7, 2.9)
		Severe	2684	27 (1.0)	(0.7, 1.5)	2684	4 (0.1)	(0.0, 0.4)
		Grade 4	2684	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Any systemic event[h]	2702	2057 (76.1)	(74.5, 77.7)	2687	1032 (38.4)	(36.6, 40.3)
		Use of antipyretic or pain medication[i]	2682	1213 (45.2)	(43.3, 47.1)	2684	320 (11.9)	(10.7, 13.2)
	Any dose	Fever						
		Any	2909	533 (18.3)	(16.9, 19.8)	2922	36 (1.2)	(0.9, 1.7)
		≥38.0°C to 38.4°C	2909	310 (10.7)	(9.6, 11.8)	2922	20 (0.7)	(0.4, 1.1)
		>38.4°C to 38.9°C	2909	163 (5.6)	(4.8, 6.5)	2922	9 (0.3)	(0.1, 0.6)
		>38.9°C to 40.0°C	2909	43 (1.5)	(1.1, 2.0)	2922	5 (0.2)	(0.1, 0.4)
		>40.0°C	2909	1 (0.0)	(0.0, 0.2)	2922	0	(0.0, 0.1)
		Unknown[d]	2909	16 (0.6)	(0.3, 0.9)	2922	2 (0.1)	(0.0, 0.2)
		Fatigue[e]						
		Any	2909	2042 (70.2)	(68.5, 71.9)	2921	1172 (40.1)	(38.3, 41.9)
		Mild	2909	673 (23.1)	(21.6, 24.7)	2921	615 (21.1)	(19.6, 22.6)
		Moderate	2909	1192 (41.0)	(39.2, 42.8)	2921	529 (18.1)	(16.7, 19.6)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Severe	2909	177 (6.1)	(5.2, 7.0)	2921	28 (1.0)	(0.6, 1.4)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		Headache[e]						
		Any	2909	1893 (65.1)	(63.3, 66.8)	2922	1229 (42.1)	(40.3, 43.9)
		Mild	2909	873 (30.0)	(28.3, 31.7)	2922	733 (25.1)	(23.5, 26.7)
		Moderate	2909	901 (31.0)	(29.3, 32.7)	2922	455 (15.6)	(14.3, 16.9)
		Severe	2909	119 (4.1)	(3.4, 4.9)	2922	41 (1.4)	(1.0, 1.9)
		Grade 4	2909	0	(0.0, 0.1)	2922	0	(0.0, 0.1)
		Chills[e]						
		Any	2909	1215 (41.8)	(40.0, 43.6)	2921	272 (9.3)	(8.3, 10.4)
		Mild	2909	598 (20.6)	(19.1, 22.1)	2921	207 (7.1)	(6.2, 8.1)
		Moderate	2909	535 (18.4)	(17.0, 19.8)	2921	61 (2.1)	(1.6, 2.7)
		Severe	2909	82 (2.8)	(2.2, 3.5)	2921	4 (0.1)	(0.0, 0.4)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		Vomiting[f]						
		Any	2909	87 (3.0)	(2.4, 3.7)	2921	60 (2.1)	(1.6, 2.6)
		Mild	2909	67 (2.3)	(1.8, 2.9)	2921	44 (1.5)	(1.1, 2.0)
		Moderate	2909	16 (0.6)	(0.3, 0.9)	2921	15 (0.5)	(0.3, 0.8)
		Severe	2909	4 (0.1)	(0.0, 0.4)	2921	1 (0.0)	(0.0, 0.2)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		Diarrhea[g]						
		Any	2909	492 (16.9)	(15.6, 18.3)	2921	462 (15.8)	(14.5, 17.2)
		Mild	2909	393 (13.5)	(12.3, 14.8)	2921	371 (12.7)	(11.5, 14.0)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Moderate	2909	90 (3.1)	(2.5, 3.8)	2921	89 (3.0)	(2.5, 3.7)
		Severe	2909	9 (0.3)	(0.1, 0.6)	2921	2 (0.1)	(0.0, 0.2)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		New or worsened muscle pain[e]						
		Any	2909	1335 (45.9)	(44.1, 47.7)	2921	471 (16.1)	(14.8, 17.5)
		Mild	2909	534 (18.4)	(17.0, 19.8)	2921	304 (10.4)	(9.3, 11.6)
		Moderate	2909	727 (25.0)	(23.4, 26.6)	2921	162 (5.5)	(4.7, 6.4)
		Severe	2909	74 (2.5)	(2.0, 3.2)	2921	5 (0.2)	(0.1, 0.4)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		New or worsened joint pain[e]						
		Any	2909	804 (27.6)	(26.0, 29.3)	2921	272 (9.3)	(8.3, 10.4)
		Mild	2909	361 (12.4)	(11.2, 13.7)	2921	161 (5.5)	(4.7, 6.4)
		Moderate	2909	411 (14.1)	(12.9, 15.4)	2921	106 (3.6)	(3.0, 4.4)
		Severe	2909	32 (1.1)	(0.8, 1.5)	2921	5 (0.2)	(0.1, 0.4)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		Any systemic event[h]	2909	2451 (84.3)	(82.9, 85.6)	2922	1798 (61.5)	(59.7, 63.3)
		Use of antipyretic or pain medication[i]	2909	1485 (51.0)	(49.2, 52.9)	2921	605 (20.7)	(19.3, 22.2)
>55 Years	1	Fever						
		Any	2008	27 (1.3)	(0.9, 2.0)	1989	9 (0.5)	(0.2, 0.9)
		≥38.0°C to 38.4°C	2008	23 (1.1)	(0.7, 1.7)	1989	3 (0.2)	(0.0, 0.4)
		>38.4°C to 38.9°C	2008	2 (0.1)	(0.0, 0.4)	1989	3 (0.2)	(0.0, 0.4)
		>38.9°C to 40.0°C	2008	1 (0.0)	(0.0, 0.3)	1989	2 (0.1)	(0.0, 0.4)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		>40.0°C	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Unknown[d]	2008	1 (0.0)	(0.0, 0.3)	1989	1 (0.1)	(0.0, 0.3)
		Fatigue[e]						
		Any	2008	677 (33.7)	(31.6, 35.8)	1989	447 (22.5)	(20.7, 24.4)
		Mild	2008	415 (20.7)	(18.9, 22.5)	1989	281 (14.1)	(12.6, 15.7)
		Moderate	2008	259 (12.9)	(11.5, 14.4)	1989	163 (8.2)	(7.0, 9.5)
		Severe	2008	3 (0.1)	(0.0, 0.4)	1989	3 (0.2)	(0.0, 0.4)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Headache[e]						
		Any	2008	503 (25.0)	(23.2, 27.0)	1990	365 (18.3)	(16.7, 20.1)
		Mild	2008	381 (19.0)	(17.3, 20.8)	1990	269 (13.5)	(12.0, 15.1)
		Moderate	2008	120 (6.0)	(5.0, 7.1)	1990	93 (4.7)	(3.8, 5.7)
		Severe	2008	2 (0.1)	(0.0, 0.4)	1990	3 (0.2)	(0.0, 0.4)
		Grade 4	2008	0	(0.0, 0.2)	1990	0	(0.0, 0.2)
		Chills[e]						
		Any	2008	131 (6.5)	(5.5, 7.7)	1989	69 (3.5)	(2.7, 4.4)
		Mild	2008	103 (5.1)	(4.2, 6.2)	1989	49 (2.5)	(1.8, 3.2)
		Moderate	2008	28 (1.4)	(0.9, 2.0)	1989	19 (1.0)	(0.6, 1.5)
		Severe	2008	0	(0.0, 0.2)	1989	1 (0.1)	(0.0, 0.3)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Vomiting[f]						
		Any	2008	10 (0.5)	(0.2, 0.9)	1989	9 (0.5)	(0.2, 0.9)
		Mild	2008	9 (0.4)	(0.2, 0.8)	1989	9 (0.5)	(0.2, 0.9)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Moderate	2008	1 (0.0)	(0.0, 0.3)	1989	0	(0.0, 0.2)
		Severe	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Diarrhea[g]						
		Any	2008	168 (8.4)	(7.2, 9.7)	1990	131 (6.6)	(5.5, 7.8)
		Mild	2008	137 (6.8)	(5.8, 8.0)	1990	110 (5.5)	(4.6, 6.6)
		Moderate	2008	27 (1.3)	(0.9, 2.0)	1990	20 (1.0)	(0.6, 1.5)
		Severe	2008	4 (0.2)	(0.1, 0.5)	1990	1 (0.1)	(0.0, 0.3)
		Grade 4	2008	0	(0.0, 0.2)	1990	0	(0.0, 0.2)
		New or worsened muscle pain[e]						
		Any	2008	274 (13.6)	(12.2, 15.2)	1989	165 (8.3)	(7.1, 9.6)
		Mild	2008	183 (9.1)	(7.9, 10.5)	1989	111 (5.6)	(4.6, 6.7)
		Moderate	2008	90 (4.5)	(3.6, 5.5)	1989	51 (2.6)	(1.9, 3.4)
		Severe	2008	1 (0.0)	(0.0, 0.3)	1989	3 (0.2)	(0.0, 0.4)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		New or worsened joint pain[e]						
		Any	2008	175 (8.7)	(7.5, 10.0)	1989	124 (6.2)	(5.2, 7.4)
		Mild	2008	119 (5.9)	(4.9, 7.0)	1989	78 (3.9)	(3.1, 4.9)
		Moderate	2008	53 (2.6)	(2.0, 3.4)	1989	45 (2.3)	(1.7, 3.0)
		Severe	2008	3 (0.1)	(0.0, 0.4)	1989	1 (0.1)	(0.0, 0.3)
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		Any systemic event[h]	2008	985 (49.1)	(46.8, 51.3)	1990	751 (37.7)	(35.6, 39.9)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Use of antipyretic or pain medication[i]	2008	382 (19.0)	(17.3, 20.8)	1989	224 (11.3)	(9.9, 12.7)
	2	Fever						
		Any	1862	224 (12.0)	(10.6, 13.6)	1833	4 (0.2)	(0.1, 0.6)
		≥38.0°C to 38.4°C	1862	158 (8.5)	(7.3, 9.8)	1833	2 (0.1)	(0.0, 0.4)
		>38.4°C to 38.9°C	1862	54 (2.9)	(2.2, 3.8)	1833	1 (0.1)	(0.0, 0.3)
		>38.9°C to 40.0°C	1862	7 (0.4)	(0.2, 0.8)	1833	1 (0.1)	(0.0, 0.3)
		>40.0°C	1862	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		Unknown[d]	1862	5 (0.3)	(0.1, 0.6)	1833	0	(0.0, 0.2)
		Fatigue[e]						
		Any	1862	952 (51.1)	(48.8, 53.4)	1834	307 (16.7)	(15.1, 18.5)
		Mild	1862	393 (21.1)	(19.3, 23.0)	1834	184 (10.0)	(8.7, 11.5)
		Moderate	1862	498 (26.7)	(24.7, 28.8)	1834	121 (6.6)	(5.5, 7.8)
		Severe	1862	60 (3.2)	(2.5, 4.1)	1834	2 (0.1)	(0.0, 0.4)
		Grade 4	1862	1 (0.1)	(0.0, 0.3)	1834	0	(0.0, 0.2)
		Headache[e]						
		Any	1867	742 (39.7)	(37.5, 42.0)	1833	259 (14.1)	(12.6, 15.8)
		Mild	1867	468 (25.1)	(23.1, 27.1)	1833	189 (10.3)	(9.0, 11.8)
		Moderate	1867	261 (14.0)	(12.4, 15.6)	1833	65 (3.5)	(2.7, 4.5)
		Severe	1867	13 (0.7)	(0.4, 1.2)	1833	5 (0.3)	(0.1, 0.6)
		Grade 4	1867	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		Chills[e]						
		Any	1864	440 (23.6)	(21.7, 25.6)	1833	57 (3.1)	(2.4, 4.0)
		Mild	1864	233 (12.5)	(11.0, 14.1)	1833	45 (2.5)	(1.8, 3.3)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Moderate	1864	186 (10.0)	(8.7, 11.4)	1833	12 (0.7)	(0.3, 1.1)
		Severe	1864	21 (1.1)	(0.7, 1.7)	1833	0	(0.0, 0.2)
		Grade 4	1864	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		Vomiting[f]						
		Any	1860	13 (0.7)	(0.4, 1.2)	1833	5 (0.3)	(0.1, 0.6)
		Mild	1860	10 (0.5)	(0.3, 1.0)	1833	5 (0.3)	(0.1, 0.6)
		Moderate	1860	1 (0.1)	(0.0, 0.3)	1833	0	(0.0, 0.2)
		Severe	1860	2 (0.1)	(0.0, 0.4)	1833	0	(0.0, 0.2)
		Grade 4	1860	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		Diarrhea[g]						
		Any	1860	154 (8.3)	(7.1, 9.6)	1834	103 (5.6)	(4.6, 6.8)
		Mild	1860	126 (6.8)	(5.7, 8.0)	1834	77 (4.2)	(3.3, 5.2)
		Moderate	1860	26 (1.4)	(0.9, 2.0)	1834	22 (1.2)	(0.8, 1.8)
		Severe	1860	2 (0.1)	(0.0, 0.4)	1834	4 (0.2)	(0.1, 0.6)
		Grade 4	1860	0	(0.0, 0.2)	1834	0	(0.0, 0.2)
		New or worsened muscle pain[e]						
		Any	1863	540 (29.0)	(26.9, 31.1)	1833	99 (5.4)	(4.4, 6.5)
		Mild	1863	229 (12.3)	(10.8, 13.9)	1833	65 (3.5)	(2.7, 4.5)
		Moderate	1863	291 (15.6)	(14.0, 17.3)	1833	33 (1.8)	(1.2, 2.5)
		Severe	1863	20 (1.1)	(0.7, 1.7)	1833	1 (0.1)	(0.0, 0.3)
		Grade 4	1863	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		New or worsened joint pain[e]						
		Any	1861	355 (19.1)	(17.3, 20.9)	1833	72 (3.9)	(3.1, 4.9)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Mild	1861	184 (9.9)	(8.6, 11.3)	1833	44 (2.4)	(1.7, 3.2)
		Moderate	1861	162 (8.7)	(7.5, 10.1)	1833	27 (1.5)	(1.0, 2.1)
		Severe	1861	9 (0.5)	(0.2, 0.9)	1833	1 (0.1)	(0.0, 0.3)
		Grade 4	1861	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		Any systemic event[h]	1868	1214 (65.0)	(62.8, 67.2)	1835	518 (28.2)	(26.2, 30.3)
		Use of antipyretic or pain medication[i]	1860	688 (37.0)	(34.8, 39.2)	1833	170 (9.3)	(8.0, 10.7)
	Any dose	Fever						
		Any	2015	238 (11.8)	(10.4, 13.3)	1994	12 (0.6)	(0.3, 1.0)
		≥38.0°C to 38.4°C	2015	168 (8.3)	(7.2, 9.6)	1994	5 (0.3)	(0.1, 0.6)
		>38.4°C to 38.9°C	2015	56 (2.8)	(2.1, 3.6)	1994	3 (0.2)	(0.0, 0.4)
		>38.9°C to 40.0°C	2015	8 (0.4)	(0.2, 0.8)	1994	3 (0.2)	(0.0, 0.4)
		>40.0°C	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		Unknown[d]	2015	6 (0.3)	(0.1, 0.6)	1994	1 (0.1)	(0.0, 0.3)
		Fatigue[e]						
		Any	2015	1148 (57.0)	(54.8, 59.1)	1994	587 (29.4)	(27.4, 31.5)
		Mild	2015	485 (24.1)	(22.2, 26.0)	1994	342 (17.2)	(15.5, 18.9)
		Moderate	2015	599 (29.7)	(27.7, 31.8)	1994	240 (12.0)	(10.6, 13.5)
		Severe	2015	63 (3.1)	(2.4, 4.0)	1994	5 (0.3)	(0.1, 0.6)
		Grade 4	2015	1 (0.0)	(0.0, 0.3)	1994	0	(0.0, 0.2)
		Headache[e]						
		Any	2015	931 (46.2)	(44.0, 48.4)	1995	494 (24.8)	(22.9, 26.7)
		Mild	2015	589 (29.2)	(27.3, 31.3)	1995	347 (17.4)	(15.8, 19.1)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Moderate	2015	327 (16.2)	(14.6, 17.9)	1995	139 (7.0)	(5.9, 8.2)
		Severe	2015	15 (0.7)	(0.4, 1.2)	1995	8 (0.4)	(0.2, 0.8)
		Grade 4	2015	0	(0.0, 0.2)	1995	0	(0.0, 0.2)
		Chills[e]						
		Any	2015	505 (25.1)	(23.2, 27.0)	1994	110 (5.5)	(4.6, 6.6)
		Mild	2015	281 (13.9)	(12.5, 15.5)	1994	80 (4.0)	(3.2, 5.0)
		Moderate	2015	203 (10.1)	(8.8, 11.5)	1994	29 (1.5)	(1.0, 2.1)
		Severe	2015	21 (1.0)	(0.6, 1.6)	1994	1 (0.1)	(0.0, 0.3)
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		Vomiting[f]						
		Any	2015	23 (1.1)	(0.7, 1.7)	1994	14 (0.7)	(0.4, 1.2)
		Mild	2015	19 (0.9)	(0.6, 1.5)	1994	14 (0.7)	(0.4, 1.2)
		Moderate	2015	2 (0.1)	(0.0, 0.4)	1994	0	(0.0, 0.2)
		Severe	2015	2 (0.1)	(0.0, 0.4)	1994	0	(0.0, 0.2)
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		Diarrhea[g]						
		Any	2015	268 (13.3)	(11.8, 14.9)	1995	201 (10.1)	(8.8, 11.5)
		Mild	2015	211 (10.5)	(9.2, 11.9)	1995	157 (7.9)	(6.7, 9.1)
		Moderate	2015	51 (2.5)	(1.9, 3.3)	1995	39 (2.0)	(1.4, 2.7)
		Severe	2015	6 (0.3)	(0.1, 0.6)	1995	5 (0.3)	(0.1, 0.6)
		Grade 4	2015	0	(0.0, 0.2)	1995	0	(0.0, 0.2)
		New or worsened muscle pain[e]						
		Any	2015	657 (32.6)	(30.6, 34.7)	1994	221 (11.1)	(9.7, 12.5)

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Mild	2015	296 (14.7)	(13.2, 16.3)	1994	138 (6.9)	(5.8, 8.1)
		Moderate	2015	340 (16.9)	(15.3, 18.6)	1994	79 (4.0)	(3.1, 4.9)
		Severe	2015	21 (1.0)	(0.6, 1.6)	1994	4 (0.2)	(0.1, 0.5)
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		New or worsened joint pain[e]						
		Any	2015	435 (21.6)	(19.8, 23.5)	1994	170 (8.5)	(7.3, 9.8)
		Mild	2015	228 (11.3)	(10.0, 12.8)	1994	98 (4.9)	(4.0, 6.0)
		Moderate	2015	195 (9.7)	(8.4, 11.1)	1994	70 (3.5)	(2.7, 4.4)
		Severe	2015	12 (0.6)	(0.3, 1.0)	1994	2 (0.1)	(0.0, 0.4)
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		Any systemic event[h]	2015	1436 (71.3)	(69.2, 73.2)	1995	922 (46.2)	(44.0, 48.4)
		Use of antipyretic or pain medication[i]	2015	816 (40.5)	(38.3, 42.7)	1994	319 (16.0)	(14.4, 17.7)

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 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

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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Age Group	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

worsened joint pain.

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

PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:24)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 sBLA CBER EDIARY/adce s020 se p3 saf

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Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
1	Fever[a]		
	n[b]	2	4
	Mean (SD)	1.5 (0.71)	1.8 (0.96)
	Median	1.5	1.5
	Min, max	(1, 2)	(1, 3)
	Fatigue		
	n[b]	22	15
	Mean (SD)	2.5 (2.11)	3.0 (2.07)
	Median	1.5	3.0
	Min, max	(1, 9)	(1, 7)
	Headache		
	n[b]	11	18
	Mean (SD)	3.0 (2.65)	2.9 (2.50)
	Median	1.0	2.0
	Min, max	(1, 7)	(1, 7)
	Unknown[c]	0	1
	Chills		
	n[b]	6	5
	Mean (SD)	2.6 (2.61)	1.8 (0.50)
	Median	1.0	2.0
	Min, max	(1, 7)	(1, 2)
	Unknown[c]	1	1
	Vomiting		

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Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
	n[b]	1	3
	Mean (SD)	1.0 (NE)	2.0 (1.00)
	Median	1.0	2.0
	Min, max	(1, 1)	(1, 3)
	Diarrhea		
	n[b]	5	8
	Mean (SD)	2.0 (1.73)	1.5 (0.76)
	Median	1.0	1.0
	Min, max	(1, 5)	(1, 3)
	New or worsened muscle pain		
	n[b]	10	10
	Mean (SD)	1.6 (0.97)	2.0 (1.94)
	Median	1.0	1.0
	Min, max	(1, 4)	(1, 7)
	New or worsened joint pain		
	n[b]	5	7
	Mean (SD)	1.4 (0.55)	2.0 (1.91)
	Median	1.0	1.0
	Min, max	(1, 2)	(1, 6)
	Use of antipyretic or pain medication		
	n[b]	7	8
	Mean (SD)	2.4 (2.15)	2.3 (1.91)
	Median	1.0	1.0
	Min, max	(1, 6)	(1, 6)

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Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
2	Fever[a]		
	n[b]	13	5
	Mean (SD)	2.0 (1.22)	1.8 (1.30)
	Median	2.0	1.0
	Min, max	(1, 5)	(1, 4)
	Fatigue		
	n[b]	26	13
	Mean (SD)	3.2 (2.54)	2.8 (1.91)
	Median	2.0	2.0
	Min, max	(1, 10)	(1, 6)
	Unknown[c]	0	1
	Headache		
	n[b]	19	12
	Mean (SD)	2.2 (1.40)	2.3 (1.56)
	Median	2.0	2.0
	Min, max	(1, 5)	(1, 5)
	Unknown[c]	0	1
	Chills		
	n[b]	16	4
	Mean (SD)	1.7 (1.08)	1.3 (0.50)
	Median	1.0	1.0
	Min, max	(1, 5)	(1, 2)
	Vomiting		
	n[b]	2	2

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Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
	Mean (SD)	2.0 (1.41)	5.5 (2.12)
	Median	2.0	5.5
	Min, max	(1, 3)	(4, 7)
	Diarrhea		
	n[b]	4	9
	Mean (SD)	2.3 (2.50)	2.1 (2.26)
	Median	1.0	1.0
	Min, max	(1, 6)	(1, 8)
	New or worsened muscle pain		
	n[b]	12	5
	Mean (SD)	2.7 (1.56)	2.2 (1.64)
	Median	2.5	2.0
	Min, max	(1, 6)	(1, 5)
	New or worsened joint pain		
	n[b]	11	5
	Mean (SD)	1.5 (0.93)	1.2 (0.45)
	Median	1.0	1.0
	Min, max	(1, 4)	(1, 2)
	Use of antipyretic or pain medication		
	n[b]	16	7
	Mean (SD)	2.0 (2.00)	1.6 (1.51)
	Median	1.0	1.0
	Min, max	(1, 6)	(1, 5)

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Duration (Days) From First to Last Day of Systemic Events (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**

Abbreviations: HIV = human immunodeficiency virus; 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 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 (22:06) Source Data: adcevd Table Generation: 29APR2021 (23:22)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 sBLA CBER EDIARY/adce s040 se dur hiv p3 saf

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Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
16-55 Years	1	Fever[a]		
		n[b]	120	25
		Mean (SD)	1.2 (0.87)	1.7 (1.52)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 7)
		Unknown[c]	0	1
		Fatigue		
		n[b]	1433	960
		Mean (SD)	2.5 (2.51)	2.9 (2.93)
		Median	1.0	2.0
		Min, max	(1, 23)	(1, 23)
		Unknown[c]	6	5
		Headache		
		n[b]	1264	976
		Mean (SD)	2.4 (2.45)	2.6 (2.62)
		Median	1.0	1.0
		Min, max	(1, 25)	(1, 22)
		Unknown[c]	5	4
		Chills		
		n[b]	481	200
		Mean (SD)	1.6 (1.35)	2.1 (2.77)
		Median	1.0	1.0
		Min, max	(1, 9)	(1, 31)
		Unknown[c]	1	2

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Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Vomiting		
		n[b]	34	36
		Mean (SD)	1.5 (1.13)	1.4 (0.91)
		Median	1.0	1.0
		Min, max	(1, 5)	(1, 4)
		Diarrhea		
		n[b]	309	324
		Mean (SD)	2.0 (2.97)	1.8 (1.91)
		Median	1.0	1.0
		Min, max	(1, 39)	(1, 23)
		Unknown[c]	1	0
		New or worsened muscle pain		
		n[b]	667	329
		Mean (SD)	1.7 (1.77)	2.0 (2.56)
		Median	1.0	1.0
		Min, max	(1, 20)	(1, 31)
		Unknown[c]	1	1
		New or worsened joint pain		
		n[b]	342	168
		Mean (SD)	1.6 (1.77)	2.2 (2.38)
		Median	1.0	1.0
		Min, max	(1, 24)	(1, 17)
		Unknown[c]	3	0
		Use of antipyretic or pain medication		

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Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		n[b]	805	398
		Mean (SD)	1.9 (1.76)	2.2 (2.44)
		Median	1.0	1.0
		Min, max	(1, 16)	(1, 23)
		Unknown[c]	1	4
	2	Fever[a]		
		n[b]	456	13
		Mean (SD)	1.2 (1.03)	2.4 (2.02)
		Median	1.0	1.0
		Min, max	(1, 19)	(1, 6)
		Unknown[c]	0	1
		Fatigue		
		n[b]	1659	617
		Mean (SD)	2.2 (2.14)	2.8 (3.04)
		Median	1.0	2.0
		Min, max	(1, 35)	(1, 38)
		Unknown[c]	5	10
		Headache		
		n[b]	1456	657
		Mean (SD)	2.2 (2.19)	2.5 (3.01)
		Median	1.0	1.0
		Min, max	(1, 42)	(1, 35)
		Unknown[c]	5	10
		Chills		

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Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		n[b]	1024	115
		Mean (SD)	1.3 (0.82)	2.2 (1.98)
		Median	1.0	1.0
		Min, max	(1, 11)	(1, 10)
		Unknown[c]	3	2
		Vomiting		
		n[b]	58	30
		Mean (SD)	2.4 (5.27)	1.5 (1.15)
		Median	1.0	1.0
		Min, max	(1, 37)	(1, 6)
		Unknown[c]	1	1
		Diarrhea		
		n[b]	269	206
		Mean (SD)	1.8 (2.31)	2.2 (3.33)
		Median	1.0	1.0
		Min, max	(1, 31)	(1, 33)
		Unknown[c]	1	3
		New or worsened muscle pain		
		n[b]	1069	237
		Mean (SD)	1.5 (1.35)	2.3 (2.71)
		Median	1.0	1.0
		Min, max	(1, 23)	(1, 27)
		Unknown[c]	3	1
		New or worsened joint pain		

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Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		n[b]	643	147
		Mean (SD)	1.6 (1.77)	2.2 (2.28)
		Median	1.0	1.0
		Min, max	(1, 28)	(1, 16)
		Unknown[c]	5	2
		Use of antipyretic or pain medication		
		n[b]	1213	320
		Mean (SD)	1.9 (2.00)	2.1 (2.83)
		Median	1.0	1.0
		Min, max	(1, 34)	(1, 38)
		Unknown[c]	6	9
>55 Years	1	Fever[a]		
		n[b]	27	9
		Mean (SD)	1.2 (0.48)	1.9 (2.32)
		Median	1.0	1.0
		Min, max	(1, 3)	(1, 8)
		Fatigue		
		n[b]	677	447
		Mean (SD)	2.4 (2.74)	2.8 (3.43)
		Median	1.0	1.0
		Min, max	(1, 34)	(1, 23)
		Unknown[c]	1	3
		Headache		
		n[b]	503	365

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Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Mean (SD)	2.0 (1.86)	2.3 (2.65)
		Median	1.0	1.0
		Min, max	(1, 17)	(1, 20)
		Unknown[c]	0	4
		Chills		
		n[b]	131	69
		Mean (SD)	1.6 (1.35)	2.1 (2.13)
		Median	1.0	1.0
		Min, max	(1, 11)	(1, 13)
		Unknown[c]	1	1
		Vomiting		
		n[b]	10	9
		Mean (SD)	1.6 (1.58)	1.5 (1.07)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 4)
		Unknown[c]	0	1
		Diarrhea		
		n[b]	168	131
		Mean (SD)	1.8 (1.58)	2.3 (3.34)
		Median	1.0	1.0
		Min, max	(1, 8)	(1, 22)
		Unknown[c]	1	0
		New or worsened muscle pain		
		n[b]	274	165

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Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Mean (SD)	1.5 (1.37)	1.9 (2.46)
		Median	1.0	1.0
		Min, max	(1, 14)	(1, 18)
		Unknown[c]	1	0
		New or worsened joint pain		
		n[b]	175	124
		Mean (SD)	1.9 (3.32)	1.9 (2.33)
		Median	1.0	1.0
		Min, max	(1, 36)	(1, 17)
		Use of antipyretic or pain medication		
		n[b]	382	224
		Mean (SD)	2.0 (2.49)	2.8 (3.27)
		Median	1.0	1.0
		Min, max	(1, 31)	(1, 22)
		Unknown[c]	5	7
	2	Fever[a]		
		n[b]	224	4
		Mean (SD)	1.1 (0.54)	1.8 (1.50)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 4)
		Fatigue		
		n[b]	952	307
		Mean (SD)	2.1 (1.88)	2.8 (4.97)
		Median	1.0	1.0

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Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Min, max	(1, 20)	(1, 69)
		Unknown[c]	3	9
		Headache		
		n[b]	742	259
		Mean (SD)	1.8 (1.43)	2.4 (2.81)
		Median	1.0	1.0
		Min, max	(1, 12)	(1, 34)
		Unknown[c]	2	3
		Chills		
		n[b]	440	57
		Mean (SD)	1.2 (0.63)	2.3 (2.72)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 16)
		Unknown[c]	1	2
		Vomiting		
		n[b]	13	5
		Mean (SD)	1.2 (0.60)	1.0 (0.00)
		Median	1.0	1.0
		Min, max	(1, 3)	(1, 1)
		Diarrhea		
		n[b]	154	103
		Mean (SD)	1.8 (1.45)	2.1 (2.83)
		Median	1.0	1.0
		Min, max	(1, 9)	(1, 26)

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Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Unknown[c]	2	2
		New or worsened muscle pain		
		n[b]	540	99
		Mean (SD)	1.4 (0.97)	1.6 (1.29)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 8)
		Unknown[c]	1	3
		New or worsened joint pain		
		n[b]	355	72
		Mean (SD)	1.6 (2.46)	2.0 (1.71)
		Median	1.0	1.0
		Min, max	(1, 32)	(1, 8)
		Unknown[c]	2	1
		Use of antipyretic or pain medication		
		n[b]	688	170
		Mean (SD)	1.8 (1.86)	2.0 (1.96)
		Median	1.0	1.0
		Min, max	(1, 30)	(1, 10)
		Unknown[c]	3	9

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 temperature recorded in e-diary.

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Duration (Days) From First to Last Day of Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**

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 (22:06) Source Data: adcevd Table Generation: 29APR2021 (23:22)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_CBER_EDIARY/adce_s040_se_dur_p3_saf

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**Onset Days for Systemic Events (Reactogenicity Subset) –
Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population**

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
1	Fever[a]		
	n[b]	2	4
	Mean (SD)	2.0 (0.00)	2.5 (2.38)
	Median	2.0	1.5
	Min, max	(2, 2)	(1, 6)
	Fatigue		
	n[b]	22	15
	Mean (SD)	1.9 (0.71)	2.8 (1.97)
	Median	2.0	2.0
	Min, max	(1, 4)	(1, 7)
	Headache		
	n[b]	11	18
	Mean (SD)	2.0 (1.34)	2.6 (1.98)
	Median	1.0	1.5
	Min, max	(1, 4)	(1, 7)
	Chills		
	n[b]	6	5
	Mean (SD)	1.8 (0.75)	2.2 (2.68)
	Median	2.0	1.0
	Min, max	(1, 3)	(1, 7)
	Vomiting		
	n[b]	1	3
	Mean (SD)	3.0 (NE)	2.0 (1.00)

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**Onset Days for Systemic Events (Reactogenicity Subset) –
Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population**

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
	Median	3.0	2.0
	Min, max	(3, 3)	(1, 3)
	Diarrhea		
	n[b]	5	8
	Mean (SD)	4.0 (2.24)	4.0 (2.00)
	Median	4.0	3.5
	Min, max	(1, 7)	(2, 7)
	New or worsened muscle pain		
	n[b]	10	10
	Mean (SD)	3.3 (1.95)	2.2 (1.40)
	Median	2.5	2.0
	Min, max	(1, 7)	(1, 5)
	New or worsened joint pain		
	n[b]	5	7
	Mean (SD)	2.8 (1.79)	3.0 (2.16)
	Median	2.0	2.0
	Min, max	(2, 6)	(1, 7)
	Any systemic event[c]		
	n[b]	33	32
	Mean (SD)	2.0 (1.38)	2.6 (1.76)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Use of antipyretic or pain medication		

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Onset Days for Systemic Events (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
	n[b]	7	8
	Mean (SD)	2.1 (0.38)	2.3 (1.49)
	Median	2.0	2.0
	Min, max	(2, 3)	(1, 5)
2	Fever[a]		
	n[b]	13	5
	Mean (SD)	2.2 (1.59)	3.8 (2.39)
	Median	2.0	4.0
	Min, max	(1, 7)	(1, 7)
	Fatigue		
	n[b]	26	13
	Mean (SD)	2.2 (1.39)	2.2 (1.36)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 6)
	Headache		
	n[b]	19	12
	Mean (SD)	2.5 (1.61)	3.9 (2.31)
	Median	2.0	4.0
	Min, max	(1, 7)	(1, 7)
	Chills		
	n[b]	16	4
	Mean (SD)	2.6 (1.63)	4.3 (2.63)
	Median	2.0	4.0
	Min, max	(1, 7)	(2, 7)

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**Onset Days for Systemic Events (Reactogenicity Subset) –
Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population**

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
	Vomiting		
	n[b]	2	2
	Mean (SD)	1.0 (0.00)	2.0 (1.41)
	Median	1.0	2.0
	Min, max	(1, 1)	(1, 3)
	Diarrhea		
	n[b]	4	9
	Mean (SD)	3.8 (2.50)	3.1 (1.96)
	Median	3.5	3.0
	Min, max	(1, 7)	(1, 7)
	New or worsened muscle pain		
	n[b]	12	5
	Mean (SD)	1.8 (0.62)	3.8 (2.49)
	Median	2.0	2.0
	Min, max	(1, 3)	(2, 7)
	New or worsened joint pain		
	n[b]	11	5
	Mean (SD)	3.0 (2.14)	4.6 (2.07)
	Median	2.0	5.0
	Min, max	(1, 7)	(2, 7)
	Any systemic event[c]		
	n[b]	39	24
	Mean (SD)	2.4 (1.60)	2.1 (1.36)
	Median	2.0	2.0

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**Onset Days for Systemic Events (Reactogenicity Subset) –
Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population**

		Vaccine Group (as Administered)	
Dose	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
	Min, max	(1, 7)	(1, 5)
	Use of antipyretic or pain medication		
	n[b]	16	7
	Mean (SD)	2.6 (1.71)	4.1 (2.12)
	Median	2.0	5.0
	Min, max	(1, 7)	(2, 7)

Abbreviations: HIV = human immunodeficiency virus; NE = not estimable.
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 (22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:22)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2_unblinded/C4591001_sBLA_CBER_EDIARY/adce_s060_se_onset_hiv_p3_saf

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Onset Days for Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
16-55 Years	1	Fever[a]		
		n[b]	120	25
		Mean (SD)	2.5 (1.24)	3.7 (2.10)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Fatigue		
		n[b]	1433	960
		Mean (SD)	2.0 (1.23)	2.3 (1.62)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[b]	1264	976
		Mean (SD)	2.4 (1.52)	2.6 (1.71)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Chills		
		n[b]	481	200
		Mean (SD)	2.2 (1.23)	2.9 (1.78)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Vomiting		
		n[b]	34	36
		Mean (SD)	3.8 (1.85)	3.6 (2.03)

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Onset Days for Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Median	4.0	4.0
		Min, max	(1, 7)	(1, 7)
		Diarrhea		
		n[b]	309	324
		Mean (SD)	3.5 (1.68)	3.6 (1.77)
		Median	3.0	3.0
		Min, max	(1, 7)	(1, 7)
		New or worsened muscle pain		
		n[b]	667	329
		Mean (SD)	2.3 (1.21)	3.1 (1.78)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		New or worsened joint pain		
		n[b]	342	168
		Mean (SD)	2.6 (1.42)	3.4 (1.61)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Any systemic event[c]		
		n[b]	1983	1560
		Mean (SD)	2.0 (1.21)	2.3 (1.59)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Use of antipyretic or pain medication		

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Onset Days for Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		n[b]	805	398
		Mean (SD)	2.4 (1.33)	3.4 (1.85)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
	2	Fever[a]		
		n[b]	456	13
		Mean (SD)	2.0 (0.55)	3.5 (2.11)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Fatigue		
		n[b]	1659	617
		Mean (SD)	1.9 (0.76)	2.4 (1.61)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[b]	1456	657
		Mean (SD)	2.1 (1.01)	2.8 (1.75)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Chills		
		n[b]	1024	115
		Mean (SD)	1.9 (0.54)	2.7 (1.64)
		Median	2.0	2.0
		Min, max	(1, 6)	(1, 7)

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Onset Days for Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Vomiting		
		n[b]	58	30
		Mean (SD)	2.6 (1.38)	3.8 (2.12)
		Median	2.0	4.0
		Min, max	(1, 7)	(1, 7)
		Diarrhea		
		n[b]	269	206
		Mean (SD)	3.2 (1.71)	3.7 (1.92)
		Median	3.0	3.0
		Min, max	(1, 7)	(1, 7)
		New or worsened muscle pain		
		n[b]	1069	237
		Mean (SD)	2.0 (0.66)	3.0 (1.83)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		New or worsened joint pain		
		n[b]	643	147
		Mean (SD)	2.1 (0.80)	3.3 (1.82)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Any systemic event[c]		
		n[b]	2057	1032
		Mean (SD)	1.8 (0.85)	2.4 (1.62)
		Median	2.0	2.0

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Onset Days for Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Min, max	(1, 7)	(1, 7)
		Use of antipyretic or pain medication		
		n[b]	1213	320
		Mean (SD)	2.0 (0.77)	3.4 (1.79)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
>55 Years	1	Fever[a]		
		n[b]	27	9
		Mean (SD)	2.4 (1.21)	3.9 (1.69)
		Median	2.0	4.0
		Min, max	(1, 6)	(2, 7)
		Fatigue		
		n[b]	677	447
		Mean (SD)	2.2 (1.27)	2.6 (1.69)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[b]	503	365
		Mean (SD)	2.5 (1.51)	2.8 (1.75)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Chills		
		n[b]	131	69

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Onset Days for Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Mean (SD)	2.5 (1.52)	3.0 (1.87)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Vomiting		
		n[b]	10	9
		Mean (SD)	3.1 (1.91)	3.7 (1.73)
		Median	2.5	4.0
		Min, max	(1, 7)	(1, 7)
		Diarrhea		
		n[b]	168	131
		Mean (SD)	3.4 (1.77)	3.6 (1.71)
		Median	3.0	3.0
		Min, max	(1, 7)	(1, 7)
		New or worsened muscle pain		
		n[b]	274	165
		Mean (SD)	2.6 (1.45)	3.5 (1.84)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		New or worsened joint pain		
		n[b]	175	124
		Mean (SD)	2.9 (1.62)	3.7 (1.78)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)

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Onset Days for Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Any systemic event[c]		
		n[b]	985	751
		Mean (SD)	2.2 (1.36)	2.6 (1.64)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Use of antipyretic or pain medication		
		n[b]	382	224
		Mean (SD)	2.6 (1.48)	3.2 (1.90)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
	2	Fever[a]		
		n[b]	224	4
		Mean (SD)	2.0 (0.35)	4.3 (2.50)
		Median	2.0	4.5
		Min, max	(1, 6)	(1, 7)
		Fatigue		
		n[b]	952	307
		Mean (SD)	2.0 (0.95)	2.8 (1.78)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[b]	742	259
		Mean (SD)	2.2 (1.12)	2.9 (1.87)
		Median	2.0	2.0

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Onset Days for Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Min, max	(1, 7)	(1, 7)
		Chills		
		n[b]	440	57
		Mean (SD)	2.0 (0.60)	3.0 (1.88)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Vomiting		
		n[b]	13	5
		Mean (SD)	3.2 (2.05)	4.2 (1.79)
		Median	2.0	4.0
		Min, max	(1, 7)	(2, 7)
		Diarrhea		
		n[b]	154	103
		Mean (SD)	3.4 (1.72)	3.5 (1.53)
		Median	3.0	3.0
		Min, max	(1, 7)	(1, 7)
		New or worsened muscle pain		
		n[b]	540	99
		Mean (SD)	2.1 (0.88)	3.1 (1.72)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		New or worsened joint pain		
		n[b]	355	72

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Onset Days for Systemic Events, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)	
Age Group	**Dose**	**Systemic Event**	**BNT162b2 (30 µg)**	**Placebo**
		Mean (SD)	2.2 (0.98)	3.5 (1.88)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Any systemic event[c]		
		n[b]	1214	518
		Mean (SD)	2.0 (0.96)	2.7 (1.73)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Use of antipyretic or pain medication		
		n[b]	688	170
		Mean (SD)	2.1 (0.93)	3.4 (1.95)
		Median	2.0	3.0
		Min, max	(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 (22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:22)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_CBER_EDIARY/adce_s060_se_onset_p3_saf

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16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
16-55	C4591001 1007 10071111	1	03AUG2020	Pain at the injection site	Mod	Sev	Mild	N		N	N	05AUG2020	3
	C4591001 1008 10081782	2	30DEC2020	Redness (cu)			21	21				02JAN2021	2
				Redness (svt)	N	N	Sev	Sev	N	N			
	C4591001 1013 10131180	1	13AUG2020	Pain at the injection site	Mod	Sev	Mild	Mild	N	Mild		19AUG2020	7
		2	03SEP2020	Redness (cu)	21							03SEP2020	1
				Redness (svt)	Sev	N							
	C4591001 1015 10151015	2	04SEP2020	Redness (cu)			18	21	21	14	13	10SEP2020	5
				Redness (svt)	N	N	Mod	Sev	Sev	Mod	Mod		
				Swelling (cu)			11	21				07SEP2020	2
				Swelling (svt)	N	N	Mod	Sev	N	N	N		
	C4591001 1015 10151030	1	15AUG2020	Pain at the injection site	Mild	Sev	Mild	Mild	N	N	N	18AUG2020	4
		2	04SEP2020	Pain at the injection site	Mod	Sev		Mild	N	Mild			
	C4591001 1016 10161087	1	10AUG2020	Swelling (cu)			>21					21AUG2020	12
				Swelling (svt)	Sev*	Sev*	Sev	Sev*	Sev*	Sev*	Sev*		
				Pain at the injection site	Mod	Mod	Sev	Mod		N	N	13AUG2020	4
	C4591001 1016 10161106	1	12AUG2020	Pain at the injection site	Mild	Sev	Mild	Mild	Mild	N		16AUG2020	5

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16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	C4591001 1056 10561108	1	01SEP2020	Swelling (cu)		11	20	21				05SEP2020	4
				Swelling (svt)		Mod	Mod	Sev	Mild*				
	C4591001 1057 10571368	1	23NOV2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	24NOV2020	2
	C4591001 1077 10771013	2	31AUG2020	Redness (cu)				>21				03SEP2020	1
				Redness (svt)	N	N	N	Sev		N	N		
				Swelling (cu)		20	20	>21		18		05SEP2020	5
				Swelling (svt)	N	Mod	Mod	Sev		Mod	N		
	C4591001 1083 10831020	2	24AUG2020	Pain at the injection site	Mild	Sev	N	N		N	N	25AUG2020	2
	C4591001 1089 10891025	2	20AUG2020	Pain at the injection site	Mild	Sev	Mod	Mild	Mild		N	24AUG2020	5
	C4591001 1089 10891107	2	02SEP2020	Redness (cu)		18	21					04SEP2020	2
				Redness (svt)	N	Mod	Sev		N	N	N		
				Swelling (cu)		18	21					04SEP2020	2
				Swelling (svt)	N	Mod	Sev		N	N	N		
	C4591001 1089 10891131	1	17AUG2020	Swelling (cu)	21							17AUG2020	1
				Swelling (svt)	Sev	N	N	N	N	N	N		
	C4591001 1090 10901043	2	24AUG2020	Pain at the injection site	Sev	Sev	Mild	N		N	Mild	01NOV2020	70
	C4591001 1091 10911046	2	25AUG2020	Redness (cu)		16	21	21				28AUG2020	3

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16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Redness (svt)	N	Mod	Sev	Sev	N	N	N		
	C4591001 1109 11091102	2	21AUG2020	Pain at the injection site	Sev	Mod	N	N	N	N	N	22AUG2020	2
	C4591001 1109 11091204	1	11AUG2020	Pain at the injection site	Mod	Sev	Mild	N	N	N	N	13AUG2020	3
	C4591001 1120 11201130	2	03SEP2020	Pain at the injection site	Sev	Mod	Mild	Mild	Mild		N	07SEP2020	5
	C4591001 1120 11201238	1	21AUG2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	22AUG2020	2
	C4591001 1124 11241039	2	03SEP2020	Swelling (cu)		21	1					04SEP2020	1
				Swelling (svt)	N	Sev	N	N	N	N	N		
				Pain at the injection site	N	Sev	Mod	N	N	N	N	05SEP2020	2
	C4591001 1125 11251243	1	08DEC2020	Pain at the injection site	Mild	Sev	Sev	Mild	N	N		11DEC2020	4
	C4591001 1127 11271014	2	19AUG2020	Pain at the injection site		Sev	Mod	Mild	Mild	Mild	N	24AUG2020	5
	C4591001 1127 11271022	1	30JUL2020	Pain at the injection site		Sev	Mod		Mild	N	N	03AUG2020	4
	C4591001 1127 11271032	1	31JUL2020	Pain at the injection site	Mod	Sev	Mild	Mild	Mild	N	N	04AUG2020	5
	C4591001 1129 11291045	2	25AUG2020	Redness (cu)		7	21					27AUG2020	2
				Redness (svt)	N	Mild	Sev		N	N			
	C4591001 1135 11351060	2	28AUG2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	30AUG2020	3

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16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	C4591001 1135 11351105	2	31AUG2020	Pain at the injection site	N	Sev	Mod	Mild	Mild	N	N	04SEP2020	4
	C4591001 1140 11401051	1	06AUG2020	Pain at the injection site	Sev	Mod	N	N	N	N	N	07AUG2020	2
	C4591001 1140 11401065	1	06AUG2020	Swelling (cu)		21	10	5				09AUG2020	3
				Swelling (svt)	N	Sev	Mild	Mild	N		N		
				Pain at the injection site	Mild	Sev	Mod	Mild	Mild		N	10AUG2020	5
		2	28AUG2020	Pain at the injection site	N	Sev	Mod	Mod	Mild	Mild		03SEP2020	6
	C4591001 1141 11411008	1	31JUL2020	Pain at the injection site	Sev*	Sev*	Sev*	Sev*	Sev*	Sev*	Sev*	21AUG2020	22
	C4591001 1142 11421316	1	24NOV2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	25NOV2020	2
	C4591001 1147 11471019	2	24AUG2020	Pain at the injection site	Mod	Sev	Mild	Mild	N	N	N	27AUG2020	4
	C4591001 1150 11501152	2	23DEC2020	Pain at the injection site	Sev	Mod	Mild				N	25DEC2020	3
	C4591001 1152 11521076	2	03SEP2020	Pain at the injection site	Mild	Sev	Mild	Mild	Mild	N	N	07SEP2020	5
	C4591001 1162 11621019	1	03AUG2020	Pain at the injection site	N	Sev	N	N	N		N	04AUG2020	1
	C4591001 1163 11631036	2	25AUG2020	Redness (cu)				21				03SEP2020	7
				Redness (svt)		N		Sev					

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16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Pain at the injection site		N		Sev				03SEP2020	7
	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 1195 11951119	1	19OCT2020	Redness (cu)	20	21	21	20	20			23OCT2020	5
				Redness (svt)	Mod	Sev	Sev	Mod	Mod	N	N		
				Swelling (cu)	21	21	21	20	20			23OCT2020	5
				Swelling (svt)	Sev	Sev	Sev	Mod	Mod	N	N		
	C4591001 1197 11971019	2	04NOV2020	Pain at the injection site	N	Sev	Mild	Mild	N	N	N	07NOV2020	3
	C4591001 1203 12031010	1	19OCT2020	Pain at the injection site	N	Sev		Mod	Mod	Mild		25OCT2020	6
	C4591001 1203 12031064	2	16NOV2020	Pain at the injection site	Sev	Mod	Mild	Mild	N	N	N	19NOV2020	4
	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 1205 12051080	2	02DEC2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	03DEC2020	2
	C4591001 1210 12101005	2	12NOV2020	Pain at the injection site		Sev	N	N	N		N	13NOV2020	1
	C4591001 1210 12101006	2	13NOV2020	Pain at the injection site	N	Sev	Mild	N	N	N	N	15NOV2020	2

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16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	C4591001 1210 12101028	1	30OCT2020	Pain at the injection site	Sev	Mild	N	N		N	N	31OCT2020	2
		2	20NOV2020	Pain at the injection site	Sev	Mild	N			N	N	21NOV2020	2
	C4591001 1210 12101033	1	02NOV2020	Pain at the injection site	Sev	Mild	Mild	Mild	Mild	N		06NOV2020	5
	C4591001 1210 12101050	2	26NOV2020	Pain at the injection site	Sev	Mild	N	N	N	N	N	27NOV2020	2
	C4591001 1212 12121007	2	17NOV2020	Pain at the injection site	Mod	Sev	Mild	Mild	N	N	N	20NOV2020	4
	C4591001 1212 12121015	2	18NOV2020	Pain at the injection site	Sev	Mod	Mod	N	N	N	N	20NOV2020	3
	C4591001 1212 12121016	2	18NOV2020	Pain at the injection site	Sev	Mild	Mild	N	N	N	N	20NOV2020	3
	C4591001 1213 12131013	2	17NOV2020	Pain at the injection site	Sev	Sev	Mod	N	N			19NOV2020	3
	C4591001 1213 12131059	1	09NOV2020	Pain at the injection site	Mod	Sev	Mild	N	N	N	N	11NOV2020	3
	C4591001 1214 12141025	1	03NOV2020	Pain at the injection site	Sev	Mod	N	N	N		N	04NOV2020	2
	C4591001 1214 12141043	1	09NOV2020	Pain at the injection site	Sev	Mild	Mild	N	N	N	N	11NOV2020	3
	C4591001 1214 12141045	1	09NOV2020	Pain at the injection site	Sev	Mild	N	N	N	N	N	10NOV2020	2
	C4591001 1217 12171002	1	22OCT2020	Pain at the injection site	Sev	Mod		Mild	Mild	N	N	26OCT2020	5

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16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	C4591001 1217 12171011	1	23OCT2020	Pain at the injection site	Sev	N	N		N	N	N	23OCT2020	1
	C4591001 1217 12171012	1	23OCT2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	25OCT2020	3
	C4591001 1217 12171016	2	16NOV2020	Pain at the injection site	Sev	Mild	N	N	N	N	N	17NOV2020	2
	C4591001 1226 12261008	2	24AUG2020	Pain at the injection site		Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1226 12261011	1	05AUG2020	Pain at the injection site	Sev	Mod	N	N	N	N		06AUG2020	2
	C4591001 1226 12261044	1	07AUG2020	Pain at the injection site	N		N	Sev	Mild	Mild	N	12AUG2020	3
	C4591001 1226 12261089	2	01SEP2020	Redness (cu)			21	21	12			05SEP2020	3
				Redness (svt)	N	N	Sev	Sev	Mod	N	N		
				Swelling (cu)			21	21				04SEP2020	2
				Swelling (svt)	N	N	Sev	Sev	N	N	N		
	C4591001 1226 12261096	1	11AUG2020	Pain at the injection site	Mild	Sev	Mild	N	N	Mild	N	16AUG2020	6
	C4591001 1226 12261140	1	12AUG2020	Pain at the injection site	N	Sev	N	N	N	N	N	13AUG2020	1
	C4591001 1226 12262255†	2	06NOV2020	Pain at the injection site	Sev*	Sev	Sev*	N	N	N	N	08NOV2020	3
	C4591001 1229 12291001	2	14OCT2020	Pain at the injection site		Sev	Mod	N	N	N	N	16OCT2020	2
	C4591001 1229 12291002	1	22SEP2020	Pain at the injection site	N	Sev	N	N	N	N	N	23SEP2020	1

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16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	C4591001 1229 12291008	2	15OCT2020	Swelling (cu)	12	21						16OCT2020	2
				Swelling (svt)	Mod	Sev	N	N	N	N	N		
	C4591001 1229 12291024†	1	28SEP2020	Redness (cu)	21							28SEP2020	1
				Redness (svt)	Sev	N	N	N	N	N	N		
				Swelling (cu)		21						29SEP2020	1
				Swelling (svt)	N	Sev	N	N	N	N	N		
	C4591001 1229 12291032	1	28SEP2020	Redness (cu)	21							28SEP2020	1
				Redness (svt)	Sev	N	N	N	N	N	N		
	C4591001 1229 12291047	1	29SEP2020	Pain at the injection site	Sev	Mild		N	N	N	N	30SEP2020	2
	C4591001 1229 12291082	1	01OCT2020	Redness (cu)	21							01OCT2020	1
				Redness (svt)	Sev	N		N	N	N			
	C4591001 1229 12291104	1	05OCT2020	Pain at the injection site	Sev	Sev	Mod	Mod	Mild			26OCT2020	22
	C4591001 1229 12291105	2	26OCT2020	Pain at the injection site	Mod	Sev	N	Mod	N	N	N	29OCT2020	4
	C4591001 1229 12291108	1	05OCT2020	Redness (cu)		21		21				08OCT2020	3
				Redness (svt)	N	Sev	N	Sev	N	N	N		
				Swelling (cu)				21				08OCT2020	1
				Swelling (svt)	N	N	N	Sev	N	N	N		

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16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	C4591001 1229 12291109	1	05OCT2020	Redness (cu)		21						06OCT2020	1
				Redness (svt)	N	Sev	N	N	N		N		
	C4591001 1229 12291114	1	06OCT2020	Redness (cu)	21							06OCT2020	1
				Redness (svt)	Sev	N	N	N	N		N		
	C4591001 1229 12291124	1	06OCT2020	Pain at the injection site	Mod	Sev	Mild	N			N	08OCT2020	3
	C4591001 1229 12291127	2	27OCT2020	Redness (cu)		21						28OCT2020	1
				Redness (svt)		Sev							
	C4591001 1230 12301018	1	24SEP2020	Pain at the injection site	Sev	Sev	Mild	N	N	N	N	26SEP2020	3
	C4591001 1230 12301021	1	24SEP2020	Redness (cu)	21							24SEP2020	1
				Redness (svt)	Sev	N	N		N	N	N		
	C4591001 1230 12301072	1	29SEP2020	Redness (cu)	21							29SEP2020	1
				Redness (svt)	Sev	N	N	N	N	N	N		
	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

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16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	C4591001 1231 12311162	1	13AUG2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	15AUG2020	3
	C4591001 1231 12311231	2	03SEP2020	Pain at the injection site	Mod	Sev	Mod	Mod	Mod	Mild	N	08SEP2020	6
	C4591001 1231 12311295	2	03SEP2020	Pain at the injection site	N	Mild	Sev	Mod	Mild	Mild		10SEP2020	7
	C4591001 1231 12311304	2	04SEP2020	Pain at the injection site		Sev	N	Mild	N	N	N	07SEP2020	3
	C4591001 1231 12311386	1	15AUG2020	Pain at the injection site	Mod	Sev	N	N	N	N	N	16AUG2020	2
	C4591001 1231 12311494	2	06SEP2020	Pain at the injection site	Sev	Mod	Mild	Mild	N	N		09SEP2020	4
	C4591001 1231 12311513	2	08SEP2020	Pain at the injection site	N	Sev	Mild	N	N	N	N	10SEP2020	2
	C4591001 1232 12321010	2	02SEP2020	Pain at the injection site		Sev	N	Mild	N	N	N	05SEP2020	3
	C4591001 1246 12461025	1	28SEP2020	Pain at the injection site	Mod	Sev	Mild	N	N	N	N	30SEP2020	3
	C4591001 1246 12461055†	1	02OCT2020	Redness (cu)	21							02OCT2020	1
				Redness (svt)	Sev	N	N	N	N	N	N		
	C4591001 1247 12471033	2	15OCT2020	Pain at the injection site	N			Sev	Sev	N	N	19OCT2020	2
	C4591001 1247 12471071	1	28SEP2020	Swelling (cu)		21						29SEP2020	1
				Swelling (svt)	N	Sev	N	N	N	N	N		

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16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	C4591001 1247 12471156	2	22OCT2020	Redness (cu)		21						23OCT2020	1
				Redness (svt)	N	Sev	N		N	N	N		
				Swelling (cu)		21						23OCT2020	1
				Swelling (svt)	N	Sev	N		N	N	N		
	C4591001 1247 12471159	1	05OCT2020	Pain at the injection site	Sev	Mild	N	N		N	N	06OCT2020	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		
18-55	C4591001 1001 10011034^	1	20MAY2020	Pain at the injection site	Sev	Mod	Mild	Mild	Mild	N	N	24MAY2020	5
	C4591001 1003 10031061^	1	22JUN2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	23JUN2020	2
>55	C4591001 1001 10011084	1	28JUL2020	Pain at the injection site	Mod	Sev	N	N	N	N	N	29JUL2020	2
	C4591001 1055 10551017	1	10AUG2020	Pain at the injection site	Mild	Sev	N		N	N	N	11AUG2020	2
	C4591001 1085 10851059	2	02SEP2020	Redness (cu)		21	15	15				05SEP2020	3
				Redness (svt)	N	Sev	Mod	Mod	N	N	N		
				Swelling (cu)		21		15				05SEP2020	3
				Swelling (svt)	N	Sev	N	Mod	N	N	N		

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16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	C4591001 1087 10871040	1	08AUG2020	Swelling (cu)		21	12	20				11AUG2020	3
				Swelling (svt)	N	Sev	Mod	Mod	N	N	N		
	C4591001 1090 10901155	2	31AUG2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	01SEP2020	2
	C4591001 1090 10901158	2	31AUG2020	Pain at the injection site	Mod	Sev	Mod	Sev	Mod	Mod	Mod	15SEP2020	16
	C4591001 1091 10911024	2	24AUG2020	Redness (cu)		3	21	15	>21			28AUG2020	3
				Redness (svt)	N	N	Sev	Mod	Sev	N	N		
	C4591001 1109 11091008	2	18AUG2020	Redness (cu)			15		21			22AUG2020	3
				Redness (svt)	N	N	Mod	N	Sev	N	N		
	C4591001 1109 11091093	2	24AUG2020	Pain at the injection site	Mod	Sev	Mod		Mild	Mild			
	C4591001 1110 11101015	1	01AUG2020	Redness (cu)		21						02AUG2020	1
				Redness (svt)	N	Sev	N	N	N	N	N		
	C4591001 1123 11231012	2	19AUG2020	Pain at the injection site		Sev	Mod	Mod	N	N	N	22AUG2020	3
	C4591001 1124 11241031	2	03SEP2020	Redness (cu)			21	20	15			07SEP2020	3
				Redness (svt)	N	N	Sev	Mod	Mod	N	N		
	C4591001 1140 11401034	1	04AUG2020	Pain at the injection site	N	Sev	N	N	N	N		05AUG2020	1
	C4591001 1142 11421044	2	29AUG2020	Swelling (cu)			21	10				01SEP2020	2

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16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Swelling (svt)	N		Sev	Mild		N	N		
	C4591001 1142 11421093	2	04SEP2020	Redness (cu)				21	21	16	16	13SEP2020	7
				Redness (svt)		N	N	Sev	Sev	Mod	Mod		
	C4591001 1145 11451012	2	02SEP2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	04SEP2020	3
	C4591001 1146 11461025	2	03SEP2020	Pain at the injection site	Sev	Mod		N	N	N	N	04SEP2020	2
	C4591001 1194 11941074	2	12NOV2020	Redness (cu)					21	>21		17NOV2020	2
				Redness (svt)					Sev	Sev	N		
				Swelling (cu)					21	>21		17NOV2020	2
				Swelling (svt)					Sev	Sev	N		
	C4591001 1195 11951046	2	05NOV2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	06NOV2020	2
	C4591001 1197 11971090	1	19OCT2020	Redness (cu)			21	9	5			23OCT2020	3
				Redness (svt)	N	N	Sev	Mild	Mild	N	N		
	C4591001 1197 11971095	2	07NOV2020	Pain at the injection site	Mod	Mod	Sev	Mild	Mild	N	N	11NOV2020	5
	C4591001 1205 12051018	2	16NOV2020	Redness (cu)		21						17NOV2020	1
				Redness (svt)		Sev	N	N		N	N		
	C4591001 1207 12071004	1	23OCT2020	Redness (cu)		11	21	5				26OCT2020	3
				Redness (svt)	N	Mod	Sev	Mild	N	N	N		

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16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
	C4591001 1224 12241016	2	02SEP2020	Redness (cu)		19	17	21	21	20	20	08SEP2020	6
				Redness (svt)	N	Mod	Mod	Sev	Sev	Mod	Mod		
	C4591001 1224 12241019	2	02SEP2020	Redness (cu)		6	21	21				05SEP2020	3
				Redness (svt)	N	Mild	Sev	Sev	N	N	N		
	C4591001 1226 12261033	1	06AUG2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	07AUG2020	2
	C4591001 1226 12261149	1	13AUG2020	Redness (cu)		21	10					15AUG2020	2
				Redness (svt)		Sev	Mild	N	N	N	N		
	C4591001 1229 12291040	2	21OCT2020	Swelling (cu)		20	21					23OCT2020	2
				Swelling (svt)	N	Mod	Sev	N	N	N	N		
	C4591001 1229 12291056	2	21OCT2020	Swelling (cu)		21						22OCT2020	1
				Swelling (svt)	N	Sev	N	N	N	N	N		
	C4591001 1229 12291067	1	30SEP2020	Redness (cu)		10		21				03OCT2020	3
				Redness (svt)	N	Mild	N	Sev		N	N		
		2	21OCT2020	Redness (cu)						21		26OCT2020	1
				Redness (svt)						Sev	N		
	C4591001 1229 12291084	2	23OCT2020	Pain at the injection site	Sev							25OCT2020	3
	C4591001 1229 12291087	1	02OCT2020	Redness (cu)			21					04OCT2020	1

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16.2.7.2.1 Listing of Severe and Grade 4 Local Reactions (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction[b]	Rel Day[a] 1	2	3	4	5	6	7	Stop Date[c]	Dur (Days)[d]
				Redness (svt)		N	Sev	N		N	N		
				Swelling (cu)		21	21					04OCT2020	2
				Swelling (svt)		Sev	Sev	N		N	N		
	C4591001 1229 12291097	1	05OCT2020	Redness (cu)	21							05OCT2020	1
				Redness (svt)	Sev	N	N	N	N	N	N		
	C4591001 1246 12461056	2	23OCT2020	Redness (cu)		21	4					24OCT2020	1
				Redness (svt)	N	Sev	N	N	N	N	N		
	C4591001 1247 12471056	2	15OCT2020	Pain at the injection site	Mod	Sev	Mod	Mild	Mild	N	N	19OCT2020	5

Abbreviations: cu = caliper units; Dur = duration; Mod = moderate; N = none; Sev = severe; svt = severity.
Note: † = Human immunodeficiency virus (HIV)-positive subject, ^ = Phase 1 subjects, * = Local reactions recorded by the investigator on the AE log page.
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 (22:11) Source Data: adfacevd Table Generation: 30APR2021 (10:23)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_CBER_EDIARY/adce_l004_sevlr_all

16.2.7.2.2 Listing of Severe and Grade 4 Local Reactions – Subjects Enrolled in Multiple Sites

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

Abbreviation: Dur = duration.

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 (22:11) Source Data: adfacevd Table Generation: 30APR2021 (10:23)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_CBER_EDIARY/adce_l004_sevlr_menrol_all

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16.2.7.2.3 Listing of Severe and Grade 4 Local Reactions – Subjects With Indeterminate Vaccine – All Subjects ≥16 Years of Age

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

Abbreviation: Dur = duration.

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 (22:11) Source Data: adfacevd Table Generation: 30APR2021 (03:41)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_CBER_EDIARY/adce_l004_sevlr_iv_all

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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]
16-55	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	Sev*			N	07AUG2020	2
				New or worsened joint pain	N	Mild	Sev	N			N	06AUG2020	2
	C4591001 1003 10031160	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1003 10031191	2	02SEP2020	Headache	Mild	Sev	Mild	N	N	Mild	N	07SEP2020	6
	C4591001 1005 10051024	2	31AUG2020	Fatigue		Sev	N	N	N		N	01SEP2020	1
	C4591001 1005 10051066	2	02SEP2020	Fatigue	N	Sev	N	N	N	N		03SEP2020	1
				Chills	N	Sev	N	N	N	N		03SEP2020	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 10061024	2	31AUG2020	Fatigue	N	Sev	Mod	N	N	N	N	02SEP2020	2
	C4591001 1006 10061037	2	04SEP2020	Fatigue	N	Sev	N		Mod	Mod	N	09SEP2020	5
	C4591001 1006 10061040	1	14AUG2020	Headache	Mild	Mild	Sev	N	N	N	Mod	21AUG2020	8

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1006 10061053	2	09SEP2020	Fatigue	Mod	Sev	Mild	Mild	Mild	Mild	Mild	16SEP2020	8
				Chills	Mod	Sev	Mild	N	N	N	N	11SEP2020	3
	C4591001 1006 10061084	2	10SEP2020	Fatigue	Sev	N				N	Mild	17SEP2020	8
	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 10071097	2	20AUG2020	New or worsened muscle pain	N	Sev	Mod	Mod	Mod	Mod	Mod	01SEP2020	12
	C4591001 1007 10071111	1	03AUG2020	Chills	N	Sev	N	N		N	N	04AUG2020	1
				New or worsened muscle pain	N	Sev	N	N		N	N	04AUG2020	1
	C4591001 1007 10071130	2	26AUG2020	Chills	N	Sev	N	N	N	N	N	27AUG2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	27AUG2020	1
	C4591001 1007 10071146	2	27AUG2020	New or worsened muscle pain	N	Sev	N		N	N	N	28AUG2020	1
	C4591001 1007 10071157	2	31AUG2020	Fatigue	N	Sev	N	N	N	N	N	01SEP2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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	N	01SEP2020	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 1011 10111035	2	03SEP2020	Fatigue	Sev	Sev	Sev	Mild	Mild	N	N	07SEP2020	5
				Headache	N	Sev	Mod	N	Mild	N	N	07SEP2020	4
				Chills	N	Sev	Mod	N	N	N	N	05SEP2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1011 10111129	2	21SEP2020	Headache	Sev	N	N	N	N		N	21SEP2020	1
	C4591001 1012 10121001	1	03AUG2020	Headache	Mild	Sev		N	N	N	N	04AUG2020	2
	C4591001 1013 10131005	1	28JUL2020	Headache	N	N	N	N	Sev		N	01AUG2020	1
	C4591001 1013 10131013	2	18AUG2020	Headache	N	Sev	Mild	Mild	Mod	Mild	N	23AUG2020	5
	C4591001 1013 10131030	2	18AUG2020	Chills	N	Sev	N	N	N	N	N	19AUG2020	1
	C4591001 1013 10131055	2	24AUG2020	New or worsened muscle pain		N	Sev	N	N		N	26AUG2020	1
	C4591001 1013 10131059	2	25AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	27AUG2020	2

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 10131062	2	24AUG2020	Fatigue	N	Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1013 10131084	2	26AUG2020	Vomiting	N	N	N	N	N	Mod	Sev	01SEP2020	2
	C4591001 1013 10131180	2	03SEP2020	New or worsened muscle pain	N	Sev						06SEP2020	2
				New or worsened joint pain	N	Sev						06SEP2020	2
	C4591001 1015 10151030	1	15AUG2020	Fatigue	N	Sev	Mod	Mild	Mild	Sev	Mod	21AUG2020	6
		2	04SEP2020	Fatigue	N	Sev		Mod	Mod	N		08SEP2020	4
				Headache	N	Sev		Mod	Mod	N		08SEP2020	4
				New or worsened muscle pain	N	Sev		Mod	N	N		07SEP2020	3
	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 10161004	2	19AUG2020	Oral temperature (°C)	36.4	39.6	37.1	36.8	36.4	36.2	35.7	20AUG2020	1
	C4591001 1016 10161078	2	28AUG2020	Headache	N	Sev	N	N	N	N	N	29AUG2020	1
				Chills	N	Sev	N	N	N	N	N	29AUG2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	29AUG2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1016 10161349	2	25NOV2020	Headache	Mod	Sev	Mild	N	N	N	N	27NOV2020	3
	C4591001 1018 10181013	1	30JUL2020	Fatigue	N	N	N	N	N	Sev	N	04AUG2020	1
	C4591001 1018 10181055	2	25AUG2020	Fatigue	N	Sev	Mod	N	Mild	Mild	Mild	31AUG2020	6
				New or worsened muscle pain	N	Sev	Mild	N	Mild	Mild	N	30AUG2020	5
	C4591001 1018 10181089	2	27AUG2020	Headache	Mild	Sev*	N	N	N	N	N	28AUG2020	2
				New or worsened joint pain	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1018 10181151	2	03SEP2020	Fatigue	Sev	Mild	N	N	N		N	04SEP2020	2
	C4591001 1042 10421070	2	31AUG2020	Fatigue	Mod	Sev	Mod	N	N	N	N	02SEP2020	3
	C4591001 1042 10421105	2	02SEP2020	Oral temperature (°C)	36.7	38.9	36.7	36.7	36.8	36.6	36.1	03SEP2020	1
	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		

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1052 10521017	1	21AUG2020	Diarrhea	N	Mild	Mod	Mod	Mod	Sev	Mod	27AUG2020	6
	C4591001 1052 10521036	1	26AUG2020	Fatigue	Mod	Sev	N	N	N		N	27AUG2020	2
	C4591001 1055 10551003	2	27AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	29AUG2020	2
	C4591001 1057 10571028	2	08SEP2020	Fatigue	N	Sev	N	N	N	N	N	09SEP2020	1
	C4591001 1057 10571362†	1	30OCT2020	Oral temperature (°C)	38.9	38.5	38.3	37.8	37.9	37.4		01NOV2020	3
				Fatigue	Mod	Mod	Sev	Mild	Mod	Sev		05NOV2020	7
				Headache	Mod	Mod	Sev	Mild	Mod	Mod		05NOV2020	7
				Vomiting	N	N	Mod	Sev	Mod	N		03NOV2020	3
	C4591001 1066 10661027	1	13AUG2020	Fatigue	Mild	N		Mod*	Sev	Mod	Mod	20AUG2020	8
	C4591001 1071 10711019	2	02SEP2020	Fatigue	N	Sev			N	N	N	03SEP2020	1
	C4591001 1071 10711039	2	04SEP2020	Headache	N	N	Mod	Sev		Mild	Mild	21SEP2020	16
	C4591001 1071 10711065	2	09SEP2020	Headache	Sev	Sev	N	N	N	N	Mild	17SEP2020	9
	C4591001 1073 10731021	1	31JUL2020	Fatigue	Mild	Sev	Mod	N		N	N	02AUG2020	3
		2	24AUG2020	Fatigue	N	Sev	Mod	N	N	N	N	26AUG2020	2
	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

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1073 10731083	2	02SEP2020	Fatigue	Mod	Sev	N	N	N		N	03SEP2020	2
				Chills	N	Sev	N	N	N		N	03SEP2020	1
	C4591001 1077 10771013	2	31AUG2020	Fatigue	N	Sev	N	Mod		Mod	N	05SEP2020	5
				Chills	N	Sev	N	N		N	N	01SEP2020	1
	C4591001 1079 10791039	2	25AUG2020	Headache	N	Mild	N	N	Mod	Sev		02SEP2020	8
	C4591001 1079 10791040	2	24AUG2020	Headache					Sev		N	28AUG2020	1
	C4591001 1079 10791097	2	31AUG2020	Chills		Sev	N	N	N		N	01SEP2020	1
	C4591001 1079 10791112	1	12AUG2020	Headache	Mild	Sev	N	N	N	N	N	13AUG2020	2
	C4591001 1079 10791115	1	12AUG2020	Headache	Mild	Mild		Mild	Sev	Mod	Mild	18AUG2020	7
	C4591001 1079 10791127	2	03SEP2020	Oral temperature (°C)	36.8	39	37.2	36.9	36.8	36.6	36.6	04SEP2020	1
	C4591001 1080 10801009	2	03SEP2020	Headache		Sev	Mod	N			N	05SEP2020	2
	C4591001 1081 10811033	2	03SEP2020	Fatigue	N	Sev	N	N	N	N		04SEP2020	1
	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 1083 10831020	2	24AUG2020	Fatigue	N	Sev	N	N		N	N	25AUG2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1083 10831060	1	06AUG2020	Oral temperature (°C)	36.5	37.8	37.8	38.6	38.6	38.9	38.7	13AUG2020	5
	C4591001 1084 10841068	2	28AUG2020	Chills	N	Sev	N					29AUG2020	1
	C4591001 1084 10841091	2	28AUG2020	Fatigue	N	Sev	N	N	N	N	N	29AUG2020	1
	C4591001 1084 10841102	2	31AUG2020	Headache	N	Sev	Mod	Mod	Mild	N	N	04SEP2020	4
	C4591001 1084 10841118	1	10AUG2020	Fatigue	N	Sev	N	N	N	N	N	11AUG2020	1
	C4591001 1084 10841146	2	02SEP2020	Fatigue	N	Sev	Mild	N	N	N	N	04SEP2020	2
	C4591001 1084 10841187	1	14AUG2020	Fatigue	Mild	Sev	Mild	N		N	N	16AUG2020	3
	C4591001 1084 10841188	1	14AUG2020	Headache	N	N	Mod	Sev	N	N	N	17AUG2020	2
		2	04SEP2020	Headache	N	N	N	N	N	N	Sev	10SEP2020	1
	C4591001 1085 10851018	1	01AUG2020	Diarrhea	N	N	N	Mod	N	Mod	Sev	07AUG2020	4
	C4591001 1085 10851075	2	29AUG2020	Fatigue	Sev	Mod	Mild	N	N	N	N	31AUG2020	3
	C4591001 1087 10871045	1	10AUG2020	Fatigue	Sev	Sev	Sev	Sev	Sev	Sev	Sev	24AUG2020	15
				New or worsened muscle pain	N	N	N	N	Mod	Mod	Sev	24AUG2020	11
		2	31AUG2020	Fatigue	Mild	Mod		Sev	Sev	Sev	Sev		
				Headache	Mild	Mod		Mod	Mod	Mod	Sev		

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1088 10881010	1	12AUG2020	Chills	N	Mild	Sev	N	N	N	N	14AUG2020	2
				Diarrhea	N	Mild	Sev	Sev	Mild	Mild	N	17AUG2020	5
	C4591001 1088 10881012	2	04SEP2020	Fatigue	N	Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1089 10891025	2	20AUG2020	Headache	N	Sev	Mod	Mod	Mild		Mild	26AUG2020	6
	C4591001 1089 10891054	1	04AUG2020	Fatigue	N	Mild	Mod		Sev		Sev	14AUG2020	10
	C4591001 1089 10891078	2	27AUG2020	Fatigue		Sev	N	N	N	N	N	28AUG2020	1
				Diarrhea		N	Sev	N	N	N	N	29AUG2020	1
	C4591001 1089 10891082	1	07AUG2020	Headache	N	Sev				N	N	08AUG2020	1
	C4591001 1089 10891103	2	31AUG2020	New or worsened joint pain	N	N	Sev	N			N	02SEP2020	1
	C4591001 1090 10901015	2	24AUG2020	Fatigue	N	Sev	N	N		N	N	25AUG2020	1
	C4591001 1090 10901022	2	28AUG2020	Headache		Sev	Mod	N	N	N	N	30AUG2020	2
	C4591001 1090 10901043	2	24AUG2020	Headache	Mild	Sev	N	N		N	Mild	30AUG2020	7
				Chills	N	Sev	N	N		N	N	25AUG2020	1
	C4591001 1090 10901045	2	24AUG2020	Headache	N	Sev	N	Mild	N	N		27AUG2020	3
				Chills	N	Sev	Mild	N	N	N		26AUG2020	2

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1090 10901050	2	24AUG2020	Fatigue	N	Sev		N	N	N	N	25AUG2020	1
				Headache	N	Sev		N	N	N	N	25AUG2020	1
				Chills	N	Sev		N	N	N	N	25AUG2020	1
				New or worsened muscle pain	N	Sev		N	N	N	N	25AUG2020	1
	C4591001 1090 10901095	1	07AUG2020	Oral temperature (°C)	36.7	37.6	39.3	36.7	36.7	37.2	36.7	09AUG2020	1
		2	28AUG2020	Oral temperature (°C)	37	39.7	38	37.3	37.1	36.4	37	30AUG2020	2
	C4591001 1090 10901104	1	07AUG2020	Fatigue	N	Mild	Sev	Mod	Mild	N	N	11AUG2020	4
				New or worsened muscle pain	N	Mod	Sev	Mod	N	N	N	10AUG2020	3
	C4591001 1091 10911037	1	04AUG2020	Fatigue	N	Sev	N	N	N	N	N	05AUG2020	1
	C4591001 1091 10911051	2	26AUG2020	Oral temperature (°C)	38.4	38.9	36.6	36.5	36.6	36.7		27AUG2020	2
	C4591001 1091 10911107	2	02SEP2020	Fatigue	Mod	Sev	N	N	N	N	N	03SEP2020	2
				Headache	Mod	Sev	N	N	N	N	N	03SEP2020	2
				Chills	N	Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1091 10911121	2	01SEP2020	Headache		Sev	N	N	N	Mild	N	06SEP2020	5
	C4591001 1094 10941016	1	14AUG2020	Fatigue	Sev	Mild	N	N		N	Sev	27AUG2020	14

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1095 10951093	2	28AUG2020	Fatigue	Mod	Sev	Mod	Mod	Mod	N	N	01SEP2020	5
	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 1107 11071065	1	06AUG2020	Oral temperature (°C)	37.1	37.3	39.6	37.1	37.2	38.2	37.8	11AUG2020	4
	C4591001 1107 11071087	2	01SEP2020	Headache	Mod	Sev	Mild	N	N	N	N	03SEP2020	3
	C4591001 1109 11091020	2	18AUG2020	Headache	Mod	Sev	N	N		N	N	19AUG2020	2
	C4591001 1109 11091027	2	21AUG2020	Fatigue		Sev	Mod	N			N	23AUG2020	2
	C4591001 1109 11091060	2	20AUG2020	Oral temperature (°C)		38.9	37	38.6	38.3	38.4		26AUG2020	6
	C4591001 1109 11091102	2	21AUG2020	Fatigue	N	Sev	N	N	N	N	N	22AUG2020	1
				Headache	N	Sev	N	N	N	N	N	22AUG2020	1
				Vomiting	N	Sev	N	N	N	Mild	N	26AUG2020	5
				New or worsened joint pain	N	Sev	N	N	N	N	N	22AUG2020	1
	C4591001 1109 11091178	2	28AUG2020	Fatigue		Sev	N	N		Mod	N	02SEP2020	5
	C4591001 1109 11091228	2	03SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	04SEP2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1109 11091246	2	08SEP2020	New or worsened muscle pain					Sev		Mod	15SEP2020	4
	C4591001 1109 11091258	2	08SEP2020	Headache		Sev	N	Mod	Mod		N	12SEP2020	4
	C4591001 1109 11091267	1	16AUG2020	Fatigue	Mod	Mod	Sev	Mod	Mod			21AUG2020	6
		2	08SEP2020	Fatigue	Sev	N	N	N	N	Mod	N	13SEP2020	6
	C4591001 1110 11101027	2	24AUG2020	Oral temperature (°C)		39.4	38.1		37.9	37.2	37.2	26AUG2020	2
				Fatigue		Sev	Mod		Mod	N	N	28AUG2020	4
				New or worsened muscle pain		Sev	Mod		N	N	N	26AUG2020	2
				New or worsened joint pain		Sev	Mod		N	N	N	26AUG2020	2
	C4591001 1110 11101033	2	25AUG2020	Fatigue	Mild	Sev		N	N	N	N	26AUG2020	2
	C4591001 1110 11101095	2	03SEP2020	Chills	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1111 11111072	2	31AUG2020	New or worsened joint pain	N	Sev	N	N	N	N	N	01SEP2020	1
	C4591001 1111 11111115	2	04SEP2020	Fatigue	Mild	N	N	Mod	Sev	Mod	Mod	10SEP2020	7
	C4591001 1112 11121045	1	03AUG2020	Oral temperature (°C)	36.9	39	37	37.1	36.9	36.8	36.6	04AUG2020	1
	C4591001 1112 11121180	2	16SEP2020	New or worsened joint pain		Sev	Sev	Mild	Mild	Mild	Mild	22SEP2020	6

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1120 11201039	2	24AUG2020	Fatigue	Mod	Sev	Mild	Mild	N	N	N	27AUG2020	4
	C4591001 1120 11201082	2	25AUG2020	Fatigue	Mild	Mild	N	Mod	Mild	Mod	Sev	02SEP2020	9
	C4591001 1120 11201103	2	25AUG2020	Fatigue	N	Sev	N	N	N	N	N	26AUG2020	1
	C4591001 1120 11201148	1	12AUG2020	Fatigue	Mild	Mod	Mild	Sev	Sev*	Mod	Mild	19AUG2020	8
		2	31AUG2020	Headache	N	Sev	N	Mild	N		N	03SEP2020	3
	C4591001 1120 11201172	1	13AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	15AUG2020	2
	C4591001 1120 11201244	2	09SEP2020	Headache		Sev	N	N	N	N	N	10SEP2020	1
	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 1120 11201278	2	02OCT2020	Chills		Sev	N	N	N	N	N	03OCT2020	1
	C4591001 1120 11201281	2	12OCT2020	New or worsened joint pain	N	N	Sev	N	N	N	N	14OCT2020	1
	C4591001 1120 11201320	2	16NOV2020	Oral temperature (°C)	32.2	38		39.6				20NOV2020	4
				Diarrhea	N	Sev		Mild				20NOV2020	4
	C4591001 1120 11201322	2	05NOV2020	Chills	N	Sev	N	N	N	N	N	06NOV2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1120 11201331	1	16OCT2020	Oral temperature (°C)	37.1	37.4	39.6		36.7	36.7		18OCT2020	1
				Headache	Mod	Mod	Sev		N	N		18OCT2020	3
				Chills	N	N	Sev		N	N		18OCT2020	1
		2	05NOV2020	Oral temperature (°C)	37.1	39.3	38.5	36.7	36.8	36.6	36.8	07NOV2020	2
	C4591001 1120 11201404	2	16NOV2020	Oral temperature (°C)	37.9	39	37.2	37.1		37.1	37.3	17NOV2020	1
				Chills	Mild	Sev	N	N		N	N	17NOV2020	2
	C4591001 1123 11231090	2	03SEP2020	Fatigue	N	Sev	N		N	N	N	04SEP2020	1
	C4591001 1124 11241019	1	12AUG2020	Fatigue	N	Sev	N	N	N	Mod	N	17AUG2020	5
	C4591001 1125 11251024	2	01SEP2020	Fatigue	N	Sev	N	N	N	N	N	02SEP2020	1
	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 1127 11271014	2	19AUG2020	Fatigue		Sev	Mod	N	Mild	Mild	N	24AUG2020	5
				Headache		Sev	N	N	N	N	N	20AUG2020	1
				New or worsened muscle pain		Sev	Mod	N	N	N	N	21AUG2020	2
	C4591001 1127 11271022	1	30JUL2020	Fatigue		Mild	Mod		Sev	Mod	Mild	16AUG2020	17

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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		Sev	Mod		Sev	Sev*	Sev*	16AUG2020	17
	C4591001 1127 11271032	1	31JUL2020	Fatigue	N	Sev	Mild	N	N	N	N	02AUG2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	01AUG2020	1
		2	19AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	21AUG2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	20AUG2020	1
	C4591001 1128 11281021	2	21AUG2020	Fatigue	N	Sev	Mod	N	N	N	N	23AUG2020	2
				Chills	N	Sev	N	N	N	N	N	22AUG2020	1
	C4591001 1128 11281024	2	20AUG2020	Fatigue	N	Sev	N	N	N	N	N	21AUG2020	1
				Headache	N	Sev	N	N	N	N	N	21AUG2020	1
	C4591001 1128 11281054	2	26AUG2020	Fatigue	Mod	Sev	N	Mod	Mod	Mod	Mod		
	C4591001 1128 11281119	2	03SEP2020	New or worsened muscle pain	Mod	Sev	N	N		N	N	04SEP2020	2
				New or worsened joint pain	Mild	Sev	N	N		N	N	04SEP2020	2
	C4591001 1129 11291006	2	17AUG2020	Fatigue		Sev	Mod	N	N	N	N	19AUG2020	2
				Chills		Sev	N	N	N	N	N	18AUG2020	1
	C4591001 1129 11291061	1	07AUG2020	Fatigue	Mod	Sev	Mod	Mild		N	N	10AUG2020	4
	C4591001 1129 11291089	1	11AUG2020	Fatigue	N	Mod	Sev		N	Mild	N	16AUG2020	5

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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	N	Sev		N	Mild	N	16AUG2020	4
	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 1133 11331051	2	24AUG2020	Oral temperature (°C)	37.1	39.4	37.4	37.2	37.2	37.3	37.2	25AUG2020	1
				Headache	N	Sev	N	N	N	N	N	25AUG2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1133 11331152	2	09SEP2020	Diarrhea	N	Sev		N	N	N		10SEP2020	1
	C4591001 1133 11331180	1	14AUG2020	Oral temperature (°C)	32.2	39.2	33.3	37.3	37.4	37.5		15AUG2020	1
		2	04SEP2020	Oral temperature (°C)	37.3	39	38.8	38.8	37.3	38	37.4	09SEP2020	5
	C4591001 1135 11351036	1	05AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	07AUG2020	2
	C4591001 1135 11351088	2	28AUG2020	Fatigue	Mild	Sev	N	N	N	N	N	29AUG2020	2
	C4591001 1135 11351114	2	01SEP2020	Fatigue	Mod	Sev		N	Mild	N	N	05SEP2020	5
				Chills	N	Sev		N	N	N	N	02SEP2020	1
				New or worsened muscle pain	N	Sev		N	N	N	N	02SEP2020	1
	C4591001 1139 11391015	2	21AUG2020	Fatigue	N	Sev	N	N	N	N	N	22AUG2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1139 11391062	2	26AUG2020	Fatigue	N	Sev	N	N	N	Mild	N	31AUG2020	5
	C4591001 1139 11391070	1	07AUG2020	Fatigue	N	Sev	N	N	N	N	N	08AUG2020	1
	C4591001 1139 11391160	2	29DEC2020	Oral temperature (°C)	36.3	38.9	36.2			36.8		30DEC2020	1
	C4591001 1140 11401022	1	03AUG2020	Fatigue	N	Sev	Mod	N	N	N	N	05AUG2020	2
				New or worsened muscle pain	Mild	Sev	Mod	N	N	N	N	05AUG2020	3
		2	25AUG2020	Oral temperature (°C)	37.8	39.8	37.3	37.1	37.2	37.2	37.1	26AUG2020	1
				Fatigue	N	Sev	Mod	N	N	N	N	27AUG2020	2
				Chills	N	Sev	N	N	N	N	N	26AUG2020	1
				New or worsened muscle pain	Mild	Sev	N	Mild	N	N	N	28AUG2020	4
	C4591001 1140 11401031	2	24AUG2020	Oral temperature (°C)	37.1	39	36.6	36.6	36.1	36.4	36.1	25AUG2020	1
				Headache	N	Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1140 11401037	2	27AUG2020	Oral temperature (°C)	36.6	39.4	36.6	36.2		35.9	35.9	28AUG2020	1
				Fatigue	Mild	Sev	Mod	N		N	N	29AUG2020	3
	C4591001 1140 11401045	2	24AUG2020	Headache	Sev	Mild	N	N	N	N	Mild	30AUG2020	7
	C4591001 1140 11401049	1	05AUG2020	Headache	N	N	N	N	N	N	Sev	12AUG2020	2

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 11401065	1	06AUG2020	New or worsened muscle pain	N	Sev	N	N	N		N	07AUG2020	1
		2	28AUG2020	New or worsened muscle pain	N	Sev	Mild	N	N	N		30AUG2020	2
				New or worsened joint pain	N	Sev	N	N	N	N		29AUG2020	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 11411026	2	24AUG2020	Fatigue		Sev	N	N	N	N	N	25AUG2020	1
				Chills		Sev	N	N	N	N	N	25AUG2020	1
				New or worsened muscle pain		Sev	N	N	N	N	N	25AUG2020	1
				New or worsened joint pain		Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1141 11411057	2	01SEP2020	Fatigue		Sev	Mild	N		N	N	03SEP2020	2
	C4591001 1141 11411081	1	14AUG2020	Fatigue	N	Sev	N	N	N	N	N	15AUG2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 11421014	2	19AUG2020	Fatigue	N	Sev		N	N	N	Mild	26AUG2020	7
	C4591001 1142 11421015	2	18AUG2020	Oral temperature (°C)			39.1		36.9	36.7	36.9	20AUG2020	1
				Headache			Sev		Mild	Mild	Mild		
				Chills			Sev		Mild	N	N	22AUG2020	3
	C4591001 1142 11421050	2	28AUG2020	Headache	N	Sev	Mild		N			30AUG2020	2
				Chills	N	Sev	N		N			29AUG2020	1
				New or worsened muscle pain	N	Sev	N		N			29AUG2020	1
	C4591001 1142 11421081	2	02SEP2020	Fatigue	N		Sev	N		N	N	04SEP2020	1
	C4591001 1142 11421336	2	23DEC2020	Headache		N	N	N	N	Sev	N	28DEC2020	1
	C4591001 1145 11451010	2	02SEP2020	Fatigue	N	Sev	Mild	N	N	N		04SEP2020	2
	C4591001 1146 11461043	2	09SEP2020	Fatigue	Sev	Mild	N	N	N	N		10SEP2020	2
	C4591001 1147 11471013	2	25AUG2020	Headache	N	N		Sev	Mod	Mild	N	30AUG2020	3
				Chills	N	N		Sev	Mod	N	N	29AUG2020	2
	C4591001 1147 11471019	2	24AUG2020	Fatigue	N	Sev	N	N	N	N	N	25AUG2020	1
				Headache	N	Sev	N	N	N	N	N	25AUG2020	1
				New or worsened muscle pain	Sev*	Sev	Sev*	Sev*	Sev*	N	N	28AUG2020	5

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 joint pain	N	Sev	N	N	N	N	N	25AUG2020	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 1149 11491016	1	07AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	09AUG2020	2
	C4591001 1149 11491049	2	01SEP2020	Oral temperature (°C)	36.6	39.4	37.9	37.3	37.1	37	37.2	02SEP2020	1
				Headache	N	Sev	N	N	N	N	N	02SEP2020	1
	C4591001 1149 11491063	2	02SEP2020	Oral temperature (°C)	37.3	39.3	37.7	37.7	37.7	37	36.8	03SEP2020	1
	C4591001 1152 11521029	2	02SEP2020	Headache	N	Sev	Mod	Mild	N	N	N	05SEP2020	3
	C4591001 1152 11521072	2	01SEP2020	Diarrhea	N	N	Sev	Mild		N	N	04SEP2020	2
	C4591001 1152 11521076	2	03SEP2020	Fatigue	Mild	Sev	N	N	N	N	N	04SEP2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	04SEP2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	04SEP2020	1
	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

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 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	19NOV2020	2
	C4591001 1157 11571006	2	04SEP2020	Fatigue		Sev	Mild	Mild	Mild	N	N	08SEP2020	4
				Chills		Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1157 11571040	2	09SEP2020	Chills	N	Sev	N	N	N	N	N	10SEP2020	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 11621103	1	13AUG2020	Headache	Sev	Mild	Mod	Mild	Mild	N	N	17AUG2020	5

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1162 11621110	2	02SEP2020	Fatigue		Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1162 11621115	2	01SEP2020	Headache			N	N	Sev			05SEP2020	1
	C4591001 1163 11631036	2	25AUG2020	Fatigue		N		Sev				03SEP2020	7
				Headache		N		Sev				03SEP2020	7
				Chills		N		Sev				03SEP2020	7
				Vomiting		N		Sev				03SEP2020	7
				Diarrhea		N		Sev				03SEP2020	7
				New or worsened muscle pain		N		Sev				03SEP2020	7
				New or worsened joint pain		N		Sev				03SEP2020	7
	C4591001 1163 11631060	1	07AUG2020	Fatigue	N	N	N	N		Sev	N	12AUG2020	1
	C4591001 1163 11631087	2	01SEP2020	Fatigue				Sev	Mild	N	N	05SEP2020	2
	C4591001 1167 11671001	2	02SEP2020	Oral temperature (°C)		39.6	36.8	36.8	36.8	36.8	36.9	03SEP2020	1
				Fatigue		Sev	N	N	N	N	N	03SEP2020	1
				Chills		Sev	N	N	N	N	N	03SEP2020	1
				New or worsened muscle pain		Sev	N	N	N	N	N	03SEP2020	1
				New or worsened joint pain		Sev	N	N	N	N	N	03SEP2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1167 11671002	2	04SEP2020	New or worsened muscle pain	N	Mod	Sev	N		N	N	06SEP2020	2
	C4591001 1167 11671006	2	02SEP2020	Fatigue	N	Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1170 11701002	2	02SEP2020	Oral temperature (°C)	37.8	41.2	37.2	36.7	37.1	36.9	36.7	03SEP2020	1
	C4591001 1171 11711020	2	04SEP2020	Fatigue		Sev	Mild	N	N	N	N	06SEP2020	2
	C4591001 1171 11711027	1	14AUG2020	Chills	N	Sev	N	N	N	N	N	15AUG2020	1
	C4591001 1177 11771039	2	09SEP2020	Chills	N	Sev	N	N	N	N	N	10SEP2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	10SEP2020	1
	C4591001 1185 11851066	2	19NOV2020	Fatigue		Sev	Mild	N		N	N	21NOV2020	2
				Headache		Sev	Mild	Mild		N	N	22NOV2020	3
				Chills		Sev	Mild	N		N	N	21NOV2020	2
				New or worsened joint pain		Sev	N	N		N	N	20NOV2020	1
	C4591001 1194 11941003	2	05NOV2020	Oral temperature (°C)	39	36.7	36.7		36.6	36.7		05NOV2020	1
	C4591001 1194 11941012	2	04NOV2020	Fatigue	N	Sev	Sev	Sev	N	N	N	07NOV2020	3
				Chills	N	Sev	Mild	N	N	N	N	06NOV2020	2
	C4591001 1194 11941030	2	07NOV2020	Oral temperature (°C)	36.8	39.1	39.1	37.4	36.8	37.1	36.2	09NOV2020	2

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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]
				Fatigue	Mild	Sev	Sev	Mild	N	N	N	10NOV2020	4
				Headache	N	Sev	Sev	Mild	N	N	N	10NOV2020	3
				Chills	Mod	Sev	Sev	N	N	N	N	09NOV2020	3
				New or worsened muscle pain	N	Mod	Sev	Mild	N	N	N	10NOV2020	3
	C4591001 1194 11941052	1	19OCT2020	Chills	N	Mild	Sev	N	N	Mild	N	24OCT2020	5
		2	09NOV2020	Chills	N	Sev	N	N	N	N	N	10NOV2020	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
	C4591001 1194 11941071	2	11NOV2020	Chills	Sev	N	N	N	N	N	N	11NOV2020	1
	C4591001 1194 11941087	1	21OCT2020	Fatigue	N	Mod	Mod	Mod	Mod	Sev	Sev	04NOV2020	14
				Headache	N	Sev	Mod	Mild	Mild	N	Mild	27OCT2020	6
	C4591001 1195 11951001	2	05NOV2020	Headache	N	Sev		N	N	N	N	06NOV2020	1
	C4591001 1195 11951010	2	03NOV2020	Fatigue	Mod	Sev	N	N	N	N	N	04NOV2020	2
	C4591001 1195 11951100	1	18OCT2020	Vomiting	Sev	N	N		N	N	N	18OCT2020	1
	C4591001 1195 11951106	2	08NOV2020	Oral temperature (°C)	36.2	39.2	38.1	37	36.2	36.2	36.1	10NOV2020	2
				Fatigue	N	Sev	Mild	N	N	N	N	10NOV2020	2

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1195 11951137	2	07NOV2020	Oral temperature (°C)	38.2	38.9	37.2	39.2	38.5	37.9	37.4	11NOV2020	5
				Fatigue	Mild	Mod	Mild	Sev	Mod	Mild	Mild	14NOV2020	8
				Headache	N	N	Mild	Mod	Sev	Mod	Mod	14NOV2020	6
	C4591001 1195 11951138	2	11NOV2020	Fatigue	N	Sev	N	N	N	N	N	12NOV2020	1
	C4591001 1197 11971096	2	07NOV2020	Headache	N	Mod	Sev	Mod	N	N	N	10NOV2020	3
	C4591001 1203 12031010	1	19OCT2020	Headache	N	Sev		Mod	Mod	N		23OCT2020	4
		2	09NOV2020	Fatigue	Mod	Sev	Mod	Mod		N		12NOV2020	4
	C4591001 1203 12031044	1	21OCT2020	Fatigue	Mild	Sev	Mild	Mild	Mild	Mild	Mod	30OCT2020	10
	C4591001 1203 12031045	2	11NOV2020	Fatigue	Mild	Sev	Mild	N		N	N	13NOV2020	3
				New or worsened muscle pain	N	Sev	Mild	N		N	N	13NOV2020	2
				New or worsened joint pain	N	Sev	Mild	N		N	N	13NOV2020	2
	C4591001 1203 12031064	1	26OCT2020	Headache	Mod	Sev	Mild	N	Mild	Mild	N	31OCT2020	6
		2	16NOV2020	Headache	Mod	Sev	Mod	Mod	N	N	N	19NOV2020	4
				New or worsened muscle pain	Sev	Mod	Mild	Mild	N	N	N	19NOV2020	4
	C4591001 1205 12051003	2	13NOV2020	Headache	Sev	N	N	N		N		13NOV2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1205 12051004	2	13NOV2020	Chills	N	N	N	N	N	Sev		25NOV2020	8
	C4591001 1205 12051010	2	13NOV2020	Diarrhea	N	N	Mild	Sev	Sev	N	N	17NOV2020	3
	C4591001 1205 12051017	1	27OCT2020	Diarrhea	N	N	N	Sev	N	N	Mod	02NOV2020	4
	C4591001 1205 12051021	2	17NOV2020	Fatigue		Sev	N	N		N	N	18NOV2020	1
				Chills		Sev	Mod	N		N	N	19NOV2020	2
	C4591001 1205 12051054	2	26NOV2020	Fatigue		Sev	N	N		N	N	27NOV2020	1
	C4591001 1205 12051077	2	02DEC2020	Fatigue	N	Sev	N	N	N		N	03DEC2020	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 1207 12071002	2	13NOV2020	New or worsened muscle pain	N	Sev	N	N		N	N	14NOV2020	1
	C4591001 1207 12071007	2	16NOV2020	Chills	Mod	Sev	N	N	N	N	N	17NOV2020	2
				New or worsened muscle pain	Mod	Sev	N	N	N	N	N	17NOV2020	2

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 joint pain	Mod	Sev	N	N	N	N	N	17NOV2020	2
	C4591001 1207 12071008	2	16NOV2020	Fatigue	N	Sev	N		N	N	N	17NOV2020	1
	C4591001 1207 12071013	1	26OCT2020	Headache	N	Sev	N	N	N	N	N	27OCT2020	1
		2	16NOV2020	Fatigue	N	Sev	Mod	N	N	N	N	18NOV2020	2
				Chills	N	Sev	N	N	N	N	N	17NOV2020	1
	C4591001 1207 12071041	2	24NOV2020	Fatigue	Mod	Sev	Mild	N	N	Mild	N	29NOV2020	6
	C4591001 1207 12071057	2	26NOV2020	Fatigue	N	Sev	N	N	N	N	N	27NOV2020	1
	C4591001 1208 12081020	1	02NOV2020	Headache	N	Mod		N	Mod	Mod	Sev	12NOV2020	10
	C4591001 1208 12081026	2	26NOV2020	Fatigue	N	Sev	Mod	N	N	N	N	28NOV2020	2
	C4591001 1208 12081034	2	26NOV2020	Fatigue		Sev	Mild	N	N	N	N	28NOV2020	2
	C4591001 1208 12081035	2	26NOV2020	Fatigue	N	Sev	N	N	N	N	N	27NOV2020	1
	C4591001 1208 12081045	2	27NOV2020	Fatigue	Mild	Sev	Mild	Sev	N	N	N	30NOV2020	4
				New or worsened muscle pain	N	Sev	Mod	Sev	N	N	N	30NOV2020	3
	C4591001 1208 12081051	2	01DEC2020	Fatigue	Mod	Sev	Mod	N		N	N	03DEC2020	3

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1208 12081052	1	10NOV2020	Headache	N	N	N	Sev	N	Mild	Mild	16NOV2020	4
	C4591001 1210 12101005	2	12NOV2020	Fatigue		Sev	N	N	N		N	13NOV2020	1
				Chills		Sev	N	N	N		N	13NOV2020	1
	C4591001 1210 12101024	1	28OCT2020	Headache	N	Sev	Mod	N	N	Mild	N	02NOV2020	5
		2	18NOV2020	Fatigue	N	Sev	Sev	Mod	Mild	N	N	22NOV2020	4
				Headache	N	Sev	Mod	Mild	N	N	N	21NOV2020	3
				Chills	N	Sev	N	N	N	N	N	19NOV2020	1
	C4591001 1210 12101028	2	20NOV2020	Fatigue	Sev	Mild	N			N	N	21NOV2020	2
	C4591001 1210 12101029	1	30OCT2020	New or worsened joint pain	N	N	N	N		Sev	N	04NOV2020	1
	C4591001 1210 12101036	2	24NOV2020	Chills	N	Sev	N	N	N	N	N	25NOV2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	25NOV2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	25NOV2020	1
	C4591001 1210 12101038	2	24NOV2020	Oral temperature (°C)		39.8	37.7	35.8	35.2	35.2	35.3	25NOV2020	1
				Fatigue		Sev	Mild	N	N	N	N	26NOV2020	2
				Headache		Sev	Mod	Mild	N	N	N	27NOV2020	3
				New or worsened joint pain		Sev	Mild	N	N	N	N	26NOV2020	2

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1210 12101047	2	24NOV2020	Fatigue	N	Sev	N	N	N	N	N	25NOV2020	1
				Headache	N	Sev	N	N	N	Mild	N	29NOV2020	5
	C4591001 1210 12101055	2	26NOV2020	Fatigue	Mod	Sev	N			N		27NOV2020	2
				Chills	Sev	Mild	N			N		27NOV2020	2
				New or worsened muscle pain	Mod	Sev	N			N		27NOV2020	2
	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 1213 12131001	2	13NOV2020	Oral temperature (°C)	39	37.8	36.7	37	36.8	36	37.2	13NOV2020	1
				Fatigue	Sev	N	N	N	N	N	N	13NOV2020	1
	C4591001 1213 12131008	1	23OCT2020	Fatigue	N	Sev	N	N	N	N	N	24OCT2020	1
		2	12NOV2020	Fatigue	Mod	Sev	N	N	N		N	13NOV2020	2
				Headache	Mod	Sev	N	N	N		N	13NOV2020	2
				New or worsened muscle pain	Mod	Sev	N	N	N		N	13NOV2020	2
	C4591001 1213 12131015	2	23NOV2020	Chills	Sev	Mild	N	Mild	N	N	N	26NOV2020	4
	C4591001 1213 12131028	2	27NOV2020	Fatigue	N	Sev	N	N	N	N	N	29NOV2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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	N	29NOV2020	1
	C4591001 1213 12131037	2	26NOV2020	Fatigue	Mod	Sev	N	N	N	N	N	27NOV2020	2
	C4591001 1213 12131038	2	24NOV2020	Headache	Mild	Sev	Mod	Mild	Mild	Mild	Mild	30NOV2020	7
	C4591001 1213 12131042	2	27NOV2020	Fatigue	Mild	Sev	N	N	N	N	N	28NOV2020	2
				Headache	N	Sev	N	N	N	N	N	28NOV2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	28NOV2020	1
	C4591001 1213 12131054	2	30NOV2020	Fatigue	N	Sev	Mild	N	N	N	N	02DEC2020	2
				Chills	N	Sev	N	N	N	N	N	01DEC2020	1
	C4591001 1214 12141004	1	23OCT2020	Fatigue	Mild	Mod	Sev	Mild	Mild	N		27OCT2020	5
	C4591001 1214 12141042	1	06NOV2020	Chills	N	Sev		N	N	N		07NOV2020	1
	C4591001 1214 12141052	2	01DEC2020	Headache	N	Mod		N	N	N	Sev	07DEC2020	6
	C4591001 1214 12141053	2	02DEC2020	Headache	N	N	N	N	N	N	Sev	08DEC2020	1
	C4591001 1217 12171002	2	12NOV2020	Fatigue	Mild	Sev	Mild	N	N	N		14NOV2020	3
	C4591001 1217 12171010	1	23OCT2020	Headache	N	N	N	Sev	N	N	N	26OCT2020	1
	C4591001 1217 12171013	1	26OCT2020	Headache	N	Mod	Sev	N	N	N	N	28OCT2020	2

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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	N	N	N	N	28OCT2020	1
	C4591001 1217 12171031	1	30OCT2020	Headache	N	N	N	Sev	N	N	N	02NOV2020	1
	C4591001 1217 12171034	2	24NOV2020	Fatigue	Mod	Sev	Mod	Mild	N	N	N	27NOV2020	4
				Chills	Mild	Sev	N	N	N	N	N	25NOV2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	25NOV2020	1
	C4591001 1217 12171051	1	06NOV2020	Fatigue	N	N	N		Sev	N	N	10NOV2020	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 1219 12191013	2	27OCT2020	Fatigue		Sev*						28OCT2020	1
	C4591001 1219 12191014	2	27OCT2020	Fatigue		Sev*						28OCT2020	1
	C4591001 1223 12231027	1	28AUG2020	Fatigue	Mild	Sev	Mild	N	N	N	N	30AUG2020	3
	C4591001 1223 12231057	1	01SEP2020	Headache	N	Sev	Mild	N	N	N	N	03SEP2020	2
	C4591001 1223 12231074	2	23SEP2020	Fatigue		Sev	N		N	N		24SEP2020	1
	C4591001 1224 12241005	1	12AUG2020	Headache	N	Mod	Sev	N	N	N	N	14AUG2020	2

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 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 12261008	1	05AUG2020	Headache	N	Sev	N	N	N	N	N	06AUG2020	1
		2	24AUG2020	Headache		Sev	N	N	N	Mild	N	29AUG2020	5
	C4591001 1226 12261019	1	06AUG2020	Fatigue	N	N	N	N	Sev	N	N	10AUG2020	1
	C4591001 1226 12261025	2	25AUG2020	Fatigue		Mild	Mod	Sev	Mild	Mod	N	30AUG2020	5
				Headache		Mild	N	Mod	Mild	Sev	N	30AUG2020	5
				New or worsened muscle pain		N	N	N	N	Sev	N	30AUG2020	1
	C4591001 1226 12261055	1	10AUG2020	Fatigue	N	N	Mild	N	Sev	Mod		16AUG2020	5

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1226 12261066	1	10AUG2020	Headache	N	Mod	Sev	N	N	N	N	12AUG2020	2
	C4591001 1226 12261072	1	11AUG2020	New or worsened muscle pain	N	N	Sev	N	N	N	N	13AUG2020	1
	C4591001 1226 12261089	1	11AUG2020	Headache	Sev	Mild	Mild	N	Mild	N	N	15AUG2020	5
	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 12261104	1	11AUG2020	Headache	Mod	Sev	Mod	Mild	Mild	N	N	15AUG2020	5
	C4591001 1226 12261106	2	01SEP2020	Fatigue	N	Sev	Sev*	Sev*	N			04SEP2020	3
				Headache	N	Sev	Sev*	Sev*	N			04SEP2020	3
				New or worsened muscle pain	N	Sev	Sev*	N	N			03SEP2020	2
				New or worsened joint pain	N	Sev	Sev*	N	N			03SEP2020	2
	C4591001 1226 12261124	2	04SEP2020	Fatigue	N	Sev	N	N	N	N		05SEP2020	1
	C4591001 1226 12261154	1	13AUG2020	Fatigue	Sev	Sev	Mild	N	N	N		15AUG2020	3

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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]
		2	16SEP2020	Headache			Sev	Mild	Mod	N	N	20SEP2020	3
	C4591001 1226 12261156	2	03SEP2020	Fatigue	N	Mod	Mod	Sev	N	N	N	06SEP2020	3
				New or worsened joint pain	N	Mod	Mild	Sev	Mild	Mod	N	08SEP2020	5
	C4591001 1226 12261208	2	08SEP2020	Headache	Sev	Mild	N	Mild	N	N	N	11SEP2020	4
	C4591001 1226 12261215	1	17AUG2020	Headache	N	Sev		N	Mild		N	21AUG2020	4
	C4591001 1226 12261232	2	09SEP2020	Fatigue	N	Sev	Mild	N	N	N	N	11SEP2020	2
	C4591001 1226 12261243	1	18AUG2020	Headache	N	N	Sev	N	N	N	N	20AUG2020	1
	C4591001 1226 12261248	2	07SEP2020	Fatigue	Mild	Sev	Mild			N	N	09SEP2020	3
	C4591001 1226 12262255†	2	06NOV2020	Fatigue		Sev		Mild	N	N	N	09NOV2020	3
				Chills	Sev*	Sev*	Sev*	N	N	N	N	08NOV2020	3
				Vomiting	Sev*	Sev*	Sev*	N	N	N	N	08NOV2020	3
				New or worsened muscle pain	Sev*	Sev*	Sev*	N	N	N	N	08NOV2020	3
	C4591001 1229 12291011	2	14OCT2020	Headache		Sev	Mod	Mod	N	N	N	17OCT2020	3
	C4591001 1229 12291016	1	25SEP2020	Headache			N	Mod	Sev	Mild	Mod	01OCT2020	4
	C4591001 1229 12291024†	1	28SEP2020	Vomiting	N	Mod	Sev	N	N	N	N	30SEP2020	2

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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]
				Diarrhea	N	Sev	Mod	Mild	N	N	N	01OCT2020	3
	C4591001 1229 12291029	1	28SEP2020	Oral temperature (°C)		39.7	33.2	35.2	35.4	35.4	35.4	29SEP2020	1
	C4591001 1229 12291042†	2	20OCT2020	Headache	Mod	Sev	N	N	N	N	N	21OCT2020	2
	C4591001 1229 12291046	2	20OCT2020	Fatigue	N	Sev	Mild		N	N	N	22OCT2020	2
	C4591001 1229 12291047	1	29SEP2020	New or worsened muscle pain	Sev	Mod		N	N	N	N	30SEP2020	2
	C4591001 1229 12291057	1	30SEP2020	Headache	N	N	N	Sev	Mild	N	N	04OCT2020	2
	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 1229 12291082	1	01OCT2020	Fatigue	Mild	Sev		N	N	N		02OCT2020	2
				New or worsened muscle pain	Sev	Mod		N	N	N		02OCT2020	2
	C4591001 1229 12291094	1	02OCT2020	Oral temperature (°C)	35.3	36.6	36.7	36.7	35.6	37.7	39.2	08OCT2020	1
	C4591001 1229 12291096†	2	23OCT2020	Headache						Mod	Sev	29OCT2020	2
	C4591001 1229 12291100	2	26OCT2020	Headache	Mod		Mild	Mild	Mild	Sev		31OCT2020	6

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 12291105	2	26OCT2020	Fatigue	Sev	Sev	Mod	Mod	Mod	Mod	Mod	03NOV2020	9
				Headache	Mod	Sev	Mod	Mod	Mod	Mod	Mod	03NOV2020	9
				Vomiting	Sev	N	N	N	N	N	N	26OCT2020	1
				New or worsened muscle pain	N	Sev	Mod	N	N	Sev	Mod	03NOV2020	8
	C4591001 1229 12291109	1	05OCT2020	Chills	N	N	N	N	N		Sev	11OCT2020	1
		2	26OCT2020	Fatigue	N	N		N	N	Sev	N	31OCT2020	1
	C4591001 1229 12291113†	2	27OCT2020	Oral temperature (°C)	40	40	40	36.4	36.1	36.4	36.6	29OCT2020	3
	C4591001 1229 12291122	1	06OCT2020	Oral temperature (°C)	39.6	39.9	39.5	39.6	39.4	39.6	39.6	12OCT2020	7
		2	27OCT2020	Oral temperature (°C)	32.6	32.8	39.2	32.5	32.8	32.9	32.7	29OCT2020	1
				Headache	Sev	Mild	N	Mild	N	N	N	30OCT2020	4
	C4591001 1230 12301001	1	23SEP2020	Headache	Sev	Sev	Mild		Mild	N	N	27SEP2020	5
	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 12301058	2	19OCT2020	Headache	N	Sev	N	N	N	N	N	20OCT2020	1
	C4591001 1230 12301074	1	30SEP2020	Headache	N	N	N	N	Sev	Mod	N	05OCT2020	2

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1230 12301084	2	21OCT2020	Oral temperature (°C)	35.3	39.4	37.2	35.9	36.3	35.6	36.4	22OCT2020	1
				Fatigue	N	Sev	Sev	N	N	N	N	23OCT2020	2
	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 1230 12301117	1	03OCT2020	Headache	N	Sev	N	N	N	N	N	04OCT2020	1
	C4591001 1230 12301124	2	27OCT2020	Headache	N	N	N	Sev	N	N	N	30OCT2020	1
	C4591001 1230 12301129	1	05OCT2020	Headache	Mild	Mild	Mild	Sev	Sev*	Mild	Mild	12OCT2020	8
	C4591001 1231 12311002	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1231 12311012	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1231 12311018	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1231 12311034	2	02SEP2020	Oral temperature (°C)	36.5	39.9	36.8	36.4	37	36.8	36.3	03SEP2020	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 12311082	1	12AUG2020	Fatigue	N	Sev	Mild	Mild	Mild	Mild	Mild	19AUG2020	7

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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	N	13AUG2020	1
		2	01SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	02SEP2020	1
	C4591001 1231 12311092	2	02SEP2020	Headache	N	Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1231 12311099	2	01SEP2020	Fatigue	Mod	Mod	Sev	Mod	Mod	Mod	Mod	12SEP2020	12
	C4591001 1231 12311124	1	13AUG2020	Headache	Mild	Sev	N	N	N	N	N	14AUG2020	2
		2	01SEP2020	Fatigue	Mild	Sev	Mod	Mild	N	N	N	04SEP2020	4
	C4591001 1231 12311125	1	13AUG2020	Headache	Mod	Sev	N	N	N	N	N	14AUG2020	2
				Chills	N	Sev	Mild	Mild	N	N	N	16AUG2020	3
	C4591001 1231 12311144	2	02SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	03SEP2020	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 12311169	2	03SEP2020	Headache	N	Sev	N	N	N		N	04SEP2020	1
	C4591001 1231 12311172	2	04SEP2020	Fatigue	N	Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1231 12311179	1	14AUG2020	Headache	N	Sev	Mild	Mild	Mild	Mild	Mild	21AUG2020	7
	C4591001 1231 12311185	1	14AUG2020	Fatigue	N	Mod	Sev	Mod	Mod	Mod	Mod	21AUG2020	7
				Chills	N	Sev	Mod	Mod	Mod	Mod	Mod	21AUG2020	7

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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]
		2	02SEP2020	Headache	Mod	Sev	N	N	N	N	N	03SEP2020	2
	C4591001 1231 12311190	2	03SEP2020	Oral temperature (°C)	36.8	39	37	36.5	36.7	36.7	36.5	04SEP2020	1
	C4591001 1231 12311193	2	04SEP2020	Chills	N	Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1231 12311208	2	04SEP2020	Headache	Mild	Sev	Mild	Mild	Mild	N	N	08SEP2020	5
	C4591001 1231 12311211	2	21SEP2020	New or worsened muscle pain	Mod	Sev	N	Sev	Mod	N	N	25SEP2020	5
				New or worsened joint pain	Mod	Sev	Mod	Mod	Mod	N	N	25SEP2020	5
	C4591001 1231 12311221	2	04SEP2020	Headache	N	Sev	Mild	N	N	Mild	N	09SEP2020	5
	C4591001 1231 12311243	2	04SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1231 12311246	2	02SEP2020	Oral temperature (°C)	37	39	37.4	36.6	36.7	36.6	37.1	03SEP2020	1
				Fatigue	N	Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1231 12311252	2	04SEP2020	Headache	N	Sev	Mild	Mild	N	N	N	07SEP2020	3
	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 12311272	2	02SEP2020	Headache	N	Sev	Mod	N	Mild	Mod	N	07SEP2020	5
	C4591001 1231 12311281	2	04SEP2020	New or worsened muscle pain	Mild	Sev	N	N	N	N	N	05SEP2020	2

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 12311289	1	15AUG2020	Headache	N	Sev	N	N	N	N	N	16AUG2020	1
	C4591001 1231 12311290	1	15AUG2020	Headache	N	Sev	N	N	N	N	N	16AUG2020	1
		2	03SEP2020	Fatigue	N	Sev	N	N	N	N	N	04SEP2020	1
				Headache	N	Sev	N	Mod	Mod	N	N	07SEP2020	4
				Chills	N	Sev	N	N	N	N	N	04SEP2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1231 12311294	1	15AUG2020	New or worsened joint pain	N	N	N	N	Sev	Mild	N	20AUG2020	2
		2	07SEP2020	Fatigue	N	N	N	N	N		Sev	14SEP2020	2
				New or worsened muscle pain	N	N	Sev	N	N		N	09SEP2020	1
	C4591001 1231 12311303	2	04SEP2020	Headache	N	Sev	N	N	N	N	N	05SEP2020	1
				Chills	Mod	Sev	N	N	N	N	N	05SEP2020	2
	C4591001 1231 12311304	2	04SEP2020	Fatigue		Sev	Mild	Mild	Mild	Mild	N	09SEP2020	5
				Chills		Sev	N	N	N	N	N	05SEP2020	1
				New or worsened muscle pain		Sev	Mild	Mild	Mild	Mild	N	09SEP2020	5
	C4591001 1231 12311306	1	15AUG2020	Headache	N	Mod	N	Sev	N	N	N	18AUG2020	3
	C4591001 1231 12311312	2	03SEP2020	Headache	Mild	Sev	N	N	N	N	N	04SEP2020	2

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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	Mod	Sev	N	N	N	N	N	04SEP2020	2
	C4591001 1231 12311317	2	07SEP2020	Headache	Sev	N	N	N	N	N	N	07SEP2020	1
	C4591001 1231 12311327	2	03SEP2020	Fatigue	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1231 12311331	2	03SEP2020	Headache	Mod	Sev	Mild	N	N	N	N	05SEP2020	3
	C4591001 1231 12311361	2	04SEP2020	Oral temperature (°C)	36.4	39	36.2	36.2	36.1	36.2	36.1	05SEP2020	1
				Fatigue	Mild	Sev	Mild	Mild	N	N	N	07SEP2020	4
				Chills	Mild	Sev	Mild	N	N	N	N	06SEP2020	3
				New or worsened joint pain	N	Sev	Mild	N	N	N	N	06SEP2020	2
	C4591001 1231 12311365	2	04SEP2020	Headache	Mild	Sev	N	N	N	N	N	05SEP2020	2
				Chills	N	Sev	N	N	N	N	N	05SEP2020	1
	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 12311370	2	03SEP2020	Headache	Mod	Sev	Mild	Mild	N	N	N	06SEP2020	4
				New or worsened muscle pain	Mild	Sev	Mod	Mild	Mild	Mild	N	08SEP2020	6
	C4591001 1231 12311375	2	03SEP2020	New or worsened muscle pain	N	Mild	N	Sev	Mild	N	N	07SEP2020	4
	C4591001 1231 12311386	1	15AUG2020	Headache	N	Sev	N	N	N	N	N	16AUG2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 12311410	1	15AUG2020	Fatigue	Mod	Mild	N	N	Mild	Sev		22AUG2020	8
				Chills	N	N	Mild	N	N	Sev		22AUG2020	6
				New or worsened muscle pain	N	N	N	N	N	Sev		22AUG2020	3
		2	06SEP2020	Fatigue	N	N	N	Sev	Mod	N	Mod	12SEP2020	4
				Headache	N	Mod	Sev	N	Mod	N	Mod	12SEP2020	6
	C4591001 1231 12311425	2	04SEP2020	Fatigue	Mild	Sev		N		N		05SEP2020	2
				New or worsened muscle pain	N	Sev		N		N		05SEP2020	1
	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 1231 12311468	2	03SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1231 12311486	2	07SEP2020	Fatigue	N	Sev	N	N	N	N	N	08SEP2020	1
				New or worsened muscle pain	N	Sev	Mild	Mild	Mod	Mild	Mod	14SEP2020	7
	C4591001 1231 12311507	2	07SEP2020	Fatigue	Mild	Sev	N	N	N	N	N	08SEP2020	2
	C4591001 1231 12311509	2	08SEP2020	Fatigue	N	Sev	N	N	N	N	N	09SEP2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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	Mild	Sev	N	N	N	N	N	09SEP2020	2
	C4591001 1232 12321010	1	13AUG2020	Fatigue							Sev	02SEP2020	15
		2	02SEP2020	Fatigue		Sev	Mild	Mild	Mild	N	Mild	08SEP2020	6
				Chills		Sev	Mod*	Mod*	N	N	N	05SEP2020	3
	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 1241 12411005	2	26AUG2020	Oral temperature (°C)		39	38.1	37.3	37.2			28AUG2020	3
	C4591001 1241 12411097	1	13AUG2020	Fatigue	N	N	N	N	Mild	Sev	Mod	20AUG2020	4
				Headache	N	N	N	N	Mod	Sev	Sev	20AUG2020	4
	C4591001 1241 12411158	2	08SEP2020	Chills	N	Sev	N	N	N	N	N	09SEP2020	1
	C4591001 1241 12411207	2	09SEP2020	Headache	N	Sev	Mod	N	N	N	N	11SEP2020	2
				New or worsened joint pain	N	Sev	N	N	N	N	N	10SEP2020	1
	C4591001 1241 12411262	2	14SEP2020	New or worsened joint pain	N	Mild	Mild	N	Sev	Mild		26SEP2020	12
	C4591001 1246 12461002	2	15OCT2020	Fatigue	N	Sev	N	N	N	N	N	16OCT2020	1
				Headache	N	Sev	N	N	N	N	N	16OCT2020	1
				Chills	N	Sev	N	N	N	N	N	16OCT2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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	16OCT2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	16OCT2020	1
	C4591001 1246 12461025	1	28SEP2020	Fatigue	N	Sev	Mild	Mod	Mild	N	Mod		
				Headache	N	Sev	Mod	Mod	Mild	N	Mod		
				Chills	N	Sev	N	N	N	N	N	29SEP2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	29SEP2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	29SEP2020	1
	C4591001 1246 12461038	2	20OCT2020	Diarrhea	N	Sev	Mild			N	N	22OCT2020	2
	C4591001 1246 12461050	2	22OCT2020	Fatigue	Mod	N	Sev	N	N	Mod		02NOV2020	12
	C4591001 1246 12461052	2	22OCT2020	Headache	N	Sev	Mod	N	N	N		24OCT2020	2
	C4591001 1246 12461055†	1	02OCT2020	Oral temperature (°C)	39.8	36.3	36	36	36.2	37.2	37	02OCT2020	1
	C4591001 1246 12461068	2	23OCT2020	Oral temperature (°C)	36.6	39.2	36.6	36.3	36.2	36.2	36.2	24OCT2020	1
	C4591001 1246 12461090	1	06OCT2020	Fatigue	Mild	Mod	Sev	N	N	N	N	08OCT2020	3
	C4591001 1247 12471010	1	23SEP2020	Headache	Mild	Mild	Mod	N	Mod	Mild	Sev	29SEP2020	7

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 12471016	2	14OCT2020	Fatigue	N	Sev		N	N			15OCT2020	1
	C4591001 1247 12471033	2	15OCT2020	New or worsened muscle pain	N			Sev	Sev	N	N	19OCT2020	2
	C4591001 1247 12471054	1	29SEP2020	Fatigue	Mod	Mod	Sev	Mod	Mod	Mod	N	04OCT2020	6
	C4591001 1247 12471099	2	20OCT2020	Fatigue	Mild	Sev	N	N	Mild	N	N	24OCT2020	5
	C4591001 1247 12471120	2	21OCT2020	Chills	N	Sev	N	N	N	N	N	22OCT2020	1
	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		
	C4591001 1247 12471145	2	22OCT2020	Headache		Mild	N		Sev	N	N	26OCT2020	4
	C4591001 1247 12471172	2	26OCT2020	Fatigue	Mild	Sev	Mild	N	Mild	N	N	30OCT2020	5
				Chills	N	Sev	N	N	N	N	N	27OCT2020	1
	C4591001 1265 12651006	2	14SEP2020	Fatigue	N	Sev	N		Mild	Mild	N	19SEP2020	5
	C4591001 1270 12701165	1	23NOV2020	Fatigue	N	Sev	N	N	N	N	N	24NOV2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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]
18-55	C4591001 1001 10011009^	2	27MAY2020	Fatigue	N	Sev	Mild	N	N	N	N	29MAY2020	2
	C4591001 1001 10011071^	2	22JUL2020	Fatigue	Mod	Sev	Mild	Mild	N	N	N	25JUL2020	4
	C4591001 1002 10021015^	2	02JUN2020	Chills	Sev	Mod	N	N	N	N	N	03JUN2020	2
	C4591001 1002 10021023^	1	18MAY2020	Fatigue	Mild	Sev	N	N	N	N	N	19MAY2020	2
				Chills	Mild	Sev	N	N	N	N	N	19MAY2020	2
				New or worsened joint pain	Mild	Sev	N	N	N	N	N	19MAY2020	2
	C4591001 1002 10021024^	1	18MAY2020	Fatigue	Mod	Sev	Mild	Mild	Mild	Mild	Mild	31MAY2020	14
				Headache	Mod	Sev	Mild	N	N	N	N	20MAY2020	3
				New or worsened muscle pain	Mod	Sev	N	N	N	N	N	19MAY2020	2
	C4591001 1003 10031061^	1	22JUN2020	Fatigue	Mod	Sev	N	N	N	N	N	23JUN2020	2
				Headache	N	Sev	N	N	N	N	N	23JUN2020	1
				Chills	N	Sev	N	N	N	N	N	23JUN2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	23JUN2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	23JUN2020	1
	C4591001 1003 10031065^	2	15JUL2020	Fatigue	N	Sev	Mild	N	N	N	N	17JUL2020	2

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 10071027^	2	08JUL2020	Fatigue	Mod	Sev		Mild	N	N		11JUL2020	4
	C4591001 1007 10071046^	1	22JUN2020	Headache	N	Mild	N		N	N	Sev	29JUN2020	7
65-85	C4591001 1001 10011043^	2	08JUL2020	Fatigue	N	Sev	N		N	N		09JUL2020	1
				Headache	N	Sev	N		N	N		09JUL2020	1
	C4591001 1001 10011048^	1	16JUN2020	Fatigue	N	Sev	Mild	N	N	N	N	18JUN2020	2
		2	08JUL2020	Oral temperature (°C)	37.1	38.9	37.6	36.7	36.7	36.5	36.7	09JUL2020	1
				Fatigue	Mild	Sev	Mild	Mild*	Mild*	Mild	Mild		
	C4591001 1001 10011063^	2	07JUL2020	Fatigue	Sev*	Sev*	N	N	N	N	N	08JUL2020	2
	C4591001 1002 10021060^	1	15JUN2020	New or worsened muscle pain	N	Sev	Sev	N	N	N	N	17JUN2020	2
	C4591001 1003 10031083^	1	01JUL2020	New or worsened muscle pain	N	Mod	Sev	N	Mod	Mod	Sev	08JUL2020	7
>55	C4591001 1001 10011084	2	18AUG2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	19AUG2020	1
	C4591001 1001 10011093	2	19AUG2020	Fatigue	N	Sev	N	N	N	N	N	20AUG2020	1
	C4591001 1001 10011142	2	25AUG2020	Diarrhea	N	Sev	Mild	Mod	N	Mild	Mild	03SEP2020	9
	C4591001 1005 10051060	2	02SEP2020	Fatigue	N	Sev	N	N	N	N	N	03SEP2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1005 10051063	2	01SEP2020	Chills	N	N	Sev	N	N	N	N	03SEP2020	1
	C4591001 1006 10061035	1	14AUG2020	Headache	N	Sev	N	Mild	N	N	N	17AUG2020	3
	C4591001 1007 10071114	1	03AUG2020	Fatigue	Mod	Mild	Sev	Sev	Mod	Mod	Mod	22AUG2020	20
				Chills	N	N	Sev	N	Mild	N	N	07AUG2020	3
	C4591001 1007 10071120	2	26AUG2020	Fatigue	Mod	Sev	Mod	Mild	N	N	N	29AUG2020	4
	C4591001 1007 10071127	1	05AUG2020	Headache	N	Mild	N	N	N	N	Sev	12AUG2020	7
	C4591001 1009 10091019	2	31AUG2020	Fatigue	N	Sev	N	N	N	N	N	01SEP2020	1
	C4591001 1011 10111014	2	03SEP2020	Fatigue	N	Sev	N	N	N			04SEP2020	1
	C4591001 1011 10111037	2	02SEP2020	Fatigue	N	Sev	Mild	N	N	N	N	04SEP2020	2
	C4591001 1013 10131184	2	03SEP2020	Fatigue	Mod	Sev	Mild	N	N	N	N	05SEP2020	3
	C4591001 1015 10151019	2	02SEP2020	New or worsened muscle pain		Mod	Sev	N	N	N		04SEP2020	2
	C4591001 1016 10161035	2	24AUG2020	Headache	N		Sev	N	Mild	Mild	N	29AUG2020	4
	C4591001 1021 10211004	2	02SEP2020	Fatigue		Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1021 10211020	1	12AUG2020	New or worsened muscle pain	N	N	N	Mod	Mod	Sev	N	17AUG2020	3

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 joint pain	N	N	N	N	N	Sev	N	17AUG2020	1
	C4591001 1022 10221006	2	04SEP2020	Chills		Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1046 10461038	2	05SEP2020	Fatigue	N	Mod	Mod	Mild	Sev	Mod	Mild	11SEP2020	6
	C4591001 1055 10551017	1	10AUG2020	Fatigue	Mild	Sev	Mild		N	N	N	12AUG2020	3
	C4591001 1057 10571330†	2	09NOV2020	Fatigue		Sev		Sev	N	N		12NOV2020	3
	C4591001 1073 10731052	2	31AUG2020	Vomiting	N	N	N	N	N	N	Sev	06SEP2020	1
	C4591001 1073 10731072	2	03SEP2020	Chills	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1073 10731078	1	12AUG2020	Diarrhea	N	Sev	Mild	N	N	N	N	14AUG2020	2
		2	03SEP2020	Fatigue	Mod	Sev	Mod	N	N	N	N	05SEP2020	3
	C4591001 1079 10791065	2	26AUG2020	Fatigue		Sev	N	N		N	N	27AUG2020	1
				New or worsened muscle pain		Sev	N	N		N	N	27AUG2020	1
	C4591001 1079 10791084	2	26AUG2020	Fatigue		Sev					N	27AUG2020	1
				Chills		Sev					N	27AUG2020	1
	C4591001 1079 10791111	2	04SEP2020	Headache		N	Sev	Mod	Mod	Mod	Mod	10SEP2020	5

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 10801006	1	10AUG2020	New or worsened muscle pain	N	N	N	N	Sev	Mod	Mod	31AUG2020	18
	C4591001 1080 10801008	2	31AUG2020	Headache	Sev*	Sev	Sev*	Mild	N	N	N	03SEP2020	4
	C4591001 1084 10841022	2	24AUG2020	Chills	N	Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1084 10841080	2	28AUG2020	Fatigue	N	Sev	N	N	N	N	N	29AUG2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	29AUG2020	1
	C4591001 1084 10841167	2	04SEP2020	Fatigue	N	Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1084 10841183	2	04SEP2020	New or worsened muscle pain	N	Sev	Mod	Mod	Mod*	N	N	08SEP2020	4
	C4591001 1085 10851074	2	27AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	29AUG2020	2
	C4591001 1087 10871001	2	25AUG2020	New or worsened joint pain	N	Mod	N	Sev	N	N	N	28AUG2020	3
	C4591001 1087 10871024	1	07AUG2020	New or worsened joint pain	N	N	N	N	N	N	Sev	13AUG2020	1
	C4591001 1087 10871039	2	31AUG2020	Fatigue	N	Sev	Mod	N	N	N	N	02SEP2020	2
	C4591001 1087 10871044	2	31AUG2020	Oral temperature (°C)	36.4	39.4	37.4	36.8		36.7	37.1	01SEP2020	1
	C4591001 1088 10881032	1	14AUG2020	New or worsened muscle pain	N	N	N	N	Sev	N	N	18AUG2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1089 10891046	2	27AUG2020	Fatigue	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1090 10901117	2	31AUG2020	Fatigue	Mod	Sev	Mild	Mild	Mild	Mild	N	05SEP2020	6
	C4591001 1090 10901124	2	31AUG2020	Chills	N	Sev	N	N	N	N	N	01SEP2020	1
	C4591001 1090 10901127	2	31AUG2020	Fatigue	Mod	Sev	Mod	Mild	Mild	Mild	Mild		
	C4591001 1090 10901171	1	13AUG2020	Diarrhea		Mild	Sev	Sev	Sev		N	17AUG2020	4
	C4591001 1091 10911059	2	27AUG2020	New or worsened muscle pain	N	N	N	Sev	N	N		30AUG2020	1
	C4591001 1096 10961002	2	04SEP2020	Diarrhea		N	Sev*	Sev	Sev*	Sev*	Sev*	10SEP2020	5
	C4591001 1107 11071043	1	05AUG2020	Fatigue	N	N	N	N	N	Sev	Mild	11AUG2020	2
				New or worsened joint pain	N	N	N	N	N	Sev	N	10AUG2020	1
	C4591001 1107 11071044	2	26AUG2020	Oral temperature (°C)	37.3	39.9	37.3	37.2	37.2	37.2	37.1	27AUG2020	1
				Fatigue	N	Sev	Mild	Mod	Mod	N	N	30AUG2020	4
				Chills	N	Sev	N	N	Mild	N	N	30AUG2020	4
	C4591001 1107 11071048	2	26AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	28AUG2020	2
	C4591001 1107 11071050	2	26AUG2020	Headache	N	Sev	Mod	Mild	N	N	N	29AUG2020	3

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1109 11091008	2	18AUG2020	Chills	N	Sev	Mild	N	N	N	N	20AUG2020	2
	C4591001 1109 11091038	2	18AUG2020	Headache	N	Sev	Sev	Mod	Mild	N	N	22AUG2020	4
	C4591001 1109 11091093	2	24AUG2020	Fatigue	N	Sev	Mild		N	N		26AUG2020	2
				Chills	N	Sev	N		N	N		25AUG2020	1
	C4591001 1109 11091166	2	24AUG2020	Diarrhea	Mild		N	Sev	N	N	N	27AUG2020	4
	C4591001 1109 11091198	2	31AUG2020	Oral temperature (°C)	38.9	37.3	37.2	37.2	37.1	37.4	37.2	31AUG2020	1
	C4591001 1110 11101056	2	28AUG2020	Fatigue	N	Sev	N	N	N		N	29AUG2020	1
	C4591001 1111 11111041	2	27AUG2020	New or worsened joint pain	N	N	N	N	Sev	N	N	31AUG2020	1
	C4591001 1111 11111073	2	31AUG2020	Fatigue	N	Sev	N	N	N	N	N	01SEP2020	1
	C4591001 1111 11111110	2	04SEP2020	Headache	N	Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1112 11121129	2	08SEP2020	Fatigue	N	Sev	Mod	Mild	Mild	Mild	Mild	15SEP2020	7
	C4591001 1112 11121145	2	08SEP2020	Fatigue	N	Sev	Mod	Mild	N	N	N	11SEP2020	3
				Chills	N	Sev	N	N	N	N	N	09SEP2020	1
	C4591001 1118 11181020	2	04SEP2020	New or worsened joint pain	N	Sev	Mod		N		N	06SEP2020	2

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1120 11201018	1	31JUL2020	Fatigue	N	N	N	N	Sev	N	N	04AUG2020	1
	C4591001 1120 11201020	2	26AUG2020	Fatigue	N	Sev	N	N	N	N	N	27AUG2020	1
	C4591001 1120 11201059	2	26AUG2020	New or worsened muscle pain	N	N	N	N	Sev	N	N	30AUG2020	1
	C4591001 1120 11201073	1	05AUG2020	Oral temperature (°C)	37.4	38	38.5	37.9	37.9	39.1	38.1	13AUG2020	8
	C4591001 1120 11201127	1	11AUG2020	Diarrhea	N	Sev*	Sev	Sev*				14AUG2020	3
	C4591001 1120 11201160	2	02SEP2020	New or worsened muscle pain		Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1120 11201214	2	08SEP2020	Headache	Mod	Mild	Mod	Mod	Sev	N	N	12SEP2020	5
	C4591001 1120 11201276	2	01OCT2020	New or worsened muscle pain		Sev	N	N	N	N		02OCT2020	1
	C4591001 1120 11201378	2	11NOV2020	Fatigue	N	Sev	N	N	N	N	N	12NOV2020	1
				Headache	N	Sev	N	N	N	N	N	12NOV2020	1
	C4591001 1120 11201408	1	28OCT2020	Fatigue	Sev	Mild	Mild	Mild			Mod	13NOV2020	17
		2	02DEC2020	New or worsened muscle pain					Sev	Mild	Mild		
				New or worsened joint pain					Sev	Mild	Mild		
	C4591001 1123 11231012	2	19AUG2020	New or worsened muscle pain		Sev	N	N	N	N	N	20AUG2020	1

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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 1124 11241031	2	03SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1124 11241033	2	01SEP2020	Fatigue		Sev	Mod	N	N	Mild	Mild	10SEP2020	9
				Chills		Sev	N	N	N	N	N	02SEP2020	1
				New or worsened muscle pain		Sev	N	N	N	N	N	02SEP2020	1
				New or worsened joint pain		Sev	N	N	N	N	N	02SEP2020	1
	C4591001 1125 11251001	2	01SEP2020	Diarrhea	N	N	N	Mod	Sev	N	N	05SEP2020	2
	C4591001 1129 11291038	2	24AUG2020	Oral temperature (°C)	36.7	38.9	36.9	36.4	36.4	36.3	36.4	25AUG2020	1
	C4591001 1129 11291099	2	31AUG2020	Fatigue	N	Mod	Sev	N	N	N	N	02SEP2020	2
	C4591001 1134 11341016	2	31AUG2020	Fatigue	Mild	Sev	Mild	Mild	Mild	Mod	Mild	08SEP2020	9
	C4591001 1135 11351028	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1135 11351046	2	27AUG2020	Fatigue	Mild	Sev	N	Mild	N	N	N	30AUG2020	4
	C4591001 1135 11351074	2	28AUG2020	Fatigue		Sev	N	N	N		N	29AUG2020	1
				Headache		Sev	N	N	N		N	29AUG2020	1
				New or worsened muscle pain		Sev	N	N	N		N	29AUG2020	1

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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 1135 11351079	2	27AUG2020	Fatigue	N	Sev	N	N	N	N	N	28AUG2020	1
				Chills	N	Sev	N	N	N	N	N	28AUG2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	28AUG2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1135 11351087	1	08AUG2020	Headache	Sev	N	N	N	N	N		08AUG2020	1
	C4591001 1135 11351116	2	01SEP2020	Chills	N	Sev	N	N	N	N		02SEP2020	1
	C4591001 1139 11391057	1	06AUG2020	Fatigue	Mild	Sev	Mild	N	N	N	N	08AUG2020	3
	C4591001 1139 11391088	2	02SEP2020	Fatigue	Mild	Sev	N	N	N		N	03SEP2020	2
	C4591001 1141 11411028	2	26AUG2020	New or worsened muscle pain	N	Mod	Sev	Mod	Mod	N	N	30AUG2020	4
	C4591001 1142 11421012	2	18AUG2020	Fatigue	N	Sev	N	N	N	N	N	19AUG2020	1
				Headache	N	Sev	Mod	N	N	N	N	20AUG2020	2
	C4591001 1145 11451009	2	02SEP2020	Fatigue	Mod	Sev	Mild	N	N	N	N	04SEP2020	3
				New or worsened muscle pain	Mild	Sev	N	N	N	N	N	03SEP2020	2
	C4591001 1147 11471009	2	24AUG2020	Fatigue	N	Mild		Mod	Sev	Mod	Mild		

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1147 11471020	2	25AUG2020	Fatigue	N	Sev	N	N	N	N	N	26AUG2020	1
	C4591001 1147 11471082	2	01SEP2020	Diarrhea		Mild	Mod	Mild	Mod	Sev	Mod	27SEP2020	26
	C4591001 1147 11471084	2	31AUG2020	Fatigue	N	Sev	N	N	N	N	Mod	07SEP2020	7
	C4591001 1147 11471116	2	01SEP2020	Oral temperature (°C)	36.9	38.9	37.7	37.1	37.6	37.2	37	02SEP2020	1
				Chills	N	Sev	Mild	N	N	N	N	03SEP2020	2
	C4591001 1147 11471124	2	04SEP2020	Fatigue	N	Mod	Mod	Mod	Sev	Mod	N	09SEP2020	5
	C4591001 1163 11631131	2	08SEP2020	New or worsened joint pain		Mild	Sev	N	N	N	N	10SEP2020	2
	C4591001 1185 11851034	2	16NOV2020	Headache	N	Mod	Sev	N	N	N	N	18NOV2020	2
	C4591001 1185 11851035	2	17NOV2020	Fatigue	N	Sev	Mild	N	N	N	N	19NOV2020	2
	C4591001 1185 11851046	1	29OCT2020	Diarrhea	N	N	Sev	Mild	N	N	N	01NOV2020	2
	C4591001 1185 11851047	2	19NOV2020	Fatigue	Mild	Sev	Mild	N	Mild	N	Mild	26NOV2020	8
	C4591001 1185 11851058	2	18NOV2020	Fatigue	N	Sev	N	N		N	N	19NOV2020	1
	C4591001 1194 11941015	2	06NOV2020	Fatigue	Mild	Sev	Mild	Mild	Mild	N	N	10NOV2020	5
				Chills	N	Sev	N	N	N	N	N	07NOV2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 11941021	2	04NOV2020	Oral temperature (°C)	37	39.4	37.8	36.4	36.6	36.6	36.4	05NOV2020	1
				Fatigue	N	Sev	Mod	Mod	Mild	N	N	08NOV2020	4
	C4591001 1194 11941036	2	06NOV2020	Fatigue	N	Sev	N	N	N	N	N	07NOV2020	1
	C4591001 1194 11941055	2	09NOV2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	10NOV2020	1
	C4591001 1194 11941073†	2	11NOV2020	Fatigue	N	N	N	N	N	N	Sev	18NOV2020	2
				Chills	N	N	N	N	N	N	Sev	18NOV2020	2
				Diarrhea	N	N	Mild	N	N	Mild	Sev	18NOV2020	6
	C4591001 1195 11951033	2	04NOV2020	Vomiting	N	Sev	N	N	N	N	N	05NOV2020	1
	C4591001 1195 11951057	2	05NOV2020	Fatigue	N	Sev	N	N	N	N	N	06NOV2020	1
	C4591001 1195 11951096	2	08NOV2020	Fatigue	N	Sev	N	N	N	N	N	09NOV2020	1
	C4591001 1197 11971006	1	15OCT2020	New or worsened joint pain	N	N	Sev	N	N	N	N	17OCT2020	1
		2	04NOV2020	Headache	N	Sev	N	N	N	N	N	05NOV2020	1
				Chills	N	Sev	N	N	N	N	N	05NOV2020	1
	C4591001 1197 11971027	2	06NOV2020	Chills	Sev	N	N	N	N	N	N	06NOV2020	1
	C4591001 1197 11971055	2	05NOV2020	Headache	Sev	Mild	N	N	N	N	N	06NOV2020	2
	C4591001 1197 11971095	2	07NOV2020	Fatigue	N	Sev	GRADE 4	Mod	N	N	N	10NOV2020	3

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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	Mod	Sev	Mod	N	N	N	10NOV2020	3
				New or worsened muscle pain	N	Mod	Sev	N	N	N	N	09NOV2020	2
				New or worsened joint pain	N	Mod	Sev	N	N	N	N	09NOV2020	2
	C4591001 1203 12031025	2	10NOV2020	Fatigue	N	Sev	N		N	N	N	11NOV2020	1
	C4591001 1205 12051018	2	16NOV2020	Fatigue		Mod	Sev	N		N	N	18NOV2020	2
	C4591001 1205 12051057	2	27NOV2020	Fatigue	N	Sev	Mild	N	Mild	N		01DEC2020	4
	C4591001 1207 12071001	2	13NOV2020	Fatigue	N	Sev	N	N	N	N	N	14NOV2020	1
	C4591001 1207 12071068	2	27NOV2020	Chills	N	Sev	Mild	N	N	N	N	29NOV2020	2
	C4591001 1213 12131027	2	23NOV2020	Oral temperature (°C)	37.9	39.5	37.6	36.7	36.7	36.5	36.5	24NOV2020	1
	C4591001 1213 12131031	2	25NOV2020	Fatigue	Mild	Sev	N	N	N	N	N	26NOV2020	2
	C4591001 1217 12171036	2	24NOV2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	25NOV2020	1
	C4591001 1224 12241003	1	12AUG2020	Diarrhea	N	N	N	Sev	N	N	N	15AUG2020	1
	C4591001 1226 12261033	2	25AUG2020	Fatigue		Sev	N	N	N	N		26AUG2020	1
				Chills		Sev	N	N	N	N		26AUG2020	1

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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 1226 12261099	2	01SEP2020	Oral temperature (°C)	36.3	39.1	36.8		36.8	36.6	36.7	02SEP2020	1
				Fatigue	N	Sev	N		N	N	N	02SEP2020	1
				Headache	N	Sev	Mild		N	N	N	03SEP2020	2
	C4591001 1229 12291023	1	25SEP2020	Oral temperature (°C)	33.2	36.2	33.1	39.6	35.8	36.1	32.4	28SEP2020	1
	C4591001 1229 12291067	2	21OCT2020	Fatigue						Sev	N	26OCT2020	1
				Diarrhea						Sev	N	26OCT2020	1
	C4591001 1229 12291084	2	23OCT2020	Fatigue	Sev							26OCT2020	4
				New or worsened muscle pain	Sev							26OCT2020	4
	C4591001 1229 12291123	1	06OCT2020	Oral temperature (°C)	38.2	39.3	37.2	36.8	37.5		36.9	07OCT2020	2
	C4591001 1230 12301096	1	01OCT2020	New or worsened muscle pain	N	N	N	N	N	Sev	N	06OCT2020	1
	C4591001 1231 12311007	2	26AUG2020	Fatigue	N	Sev	N	N	N	N	N	27AUG2020	1
				Chills	N	Sev	N	N	N	N	N	27AUG2020	1
	C4591001 1231 12311038	1	11AUG2020	Headache	N	Sev	N	Mild	Mild	N	N	15AUG2020	4
	C4591001 1231 12311146	2	03SEP2020	Fatigue	N	Sev	N	N	N	N	N	04SEP2020	1
				Chills	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1231 12311150	2	01SEP2020	Fatigue	N	Sev	Mod	N	N	N	N	03SEP2020	2

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16.2.7.3.1 Listing of Severe and Grade 4 Systemic Events (Reactogenicity Subset) – All Subjects ≥16 Years of Age – Safety Population

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	Mod	Mild	N	N	N	04SEP2020	3
				New or worsened joint pain	N	Sev	Mod	N	N	N	N	03SEP2020	2
	C4591001 1231 12311292	2	03SEP2020	Fatigue	N	Mod	Mild	Mod	Mild	N	Sev	12SEP2020	9
				New or worsened joint pain	N	N	N	N	N	N	Sev	12SEP2020	4
	C4591001 1231 12311329	2	04SEP2020	Headache	N	Mod	N	Sev	Sev	Sev	Mod		
	C4591001 1231 12311390	1	15AUG2020	Headache	Mild	Sev	Mild	N	N	Mild	Mild	22AUG2020	8

Abbreviations: Dur = duration; Mod = moderate; N = none; Sev = severe.
Note: † = Human immunodeficiency virus (HIV)-positive subject, ^ = Phase 1 subjects, * = 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 electronic diary (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 (22:11) Source Data: adfacevd Table Generation: 30APR2021 (10:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 sBLA CBER EDIARY/adce l004 sevse all

16.2.7.3.2 Listing of Severe and Grade 4 Systemic Events – Subjects Enrolled in Multiple Sites

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]
No subject meets the reporting criteria.													

Abbreviation: Dur = duration.

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 electronic diary (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 (22:11) Source Data: adfacevd Table Generation: 30APR2021 (10:18)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_CBER_EDIARY/adce_l004_sevse_menrol_all

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16.2.7.3.3 Listing of Severe and Grade 4 Systemic Events – Subjects With Indeterminate Vaccine – All Subjects ≥16 Years of Age

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]
No subject meets the reporting criteria.													

Abbreviation: Dur = duration.

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 electronic diary (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 (22:11) Source Data: adfacevd Table Generation: 30APR2021 (03:41)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 sBLA CBER EDIARY/adce l004 sevse iv all

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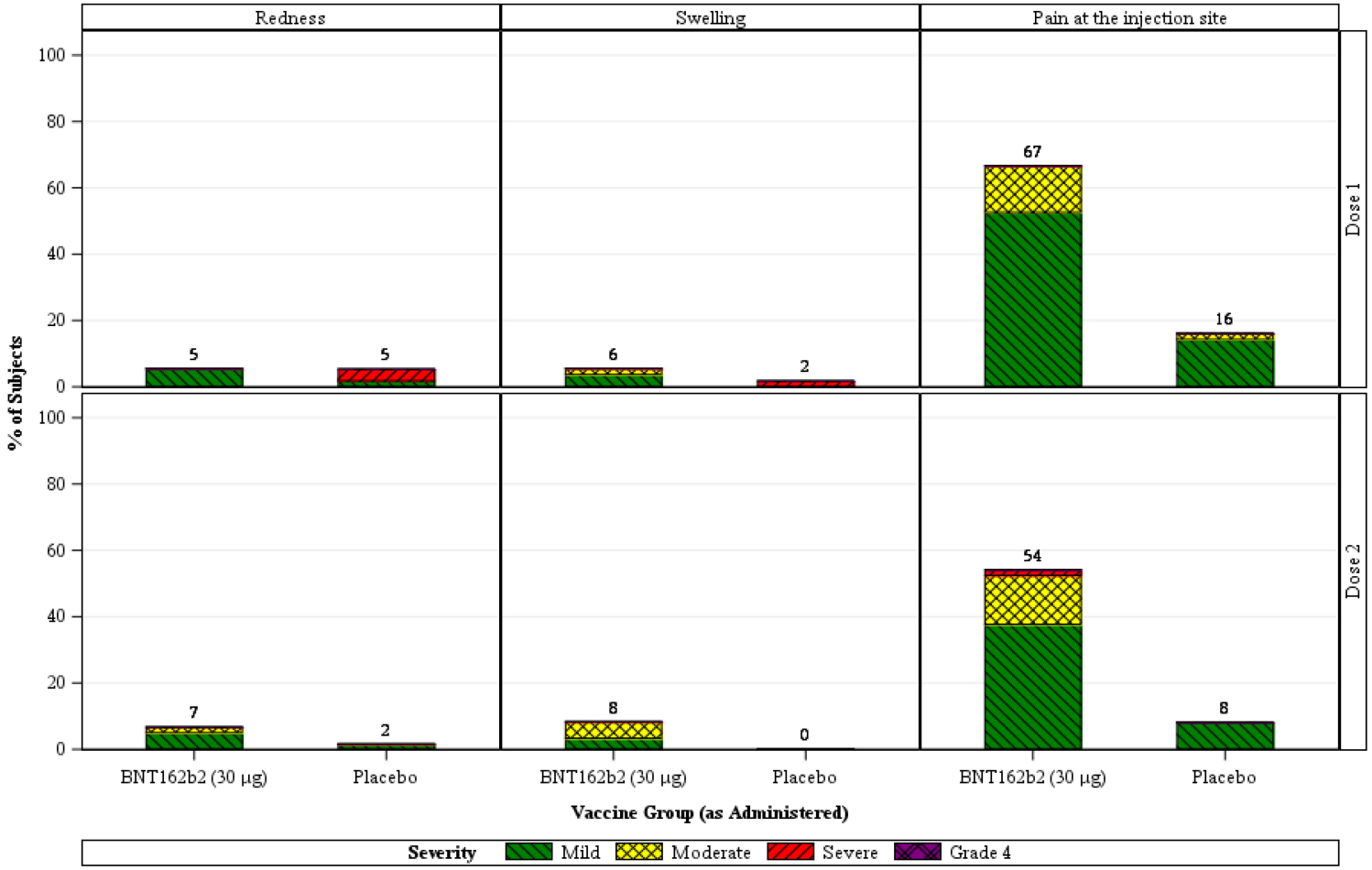
Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) –
Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population



Abbreviation: HIV = human immunodeficiency virus.
Note: Number above each bar denotes percentage of subjects reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:24)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_CBER_EDIARY/adce_f001_lr_max_hiv_p3

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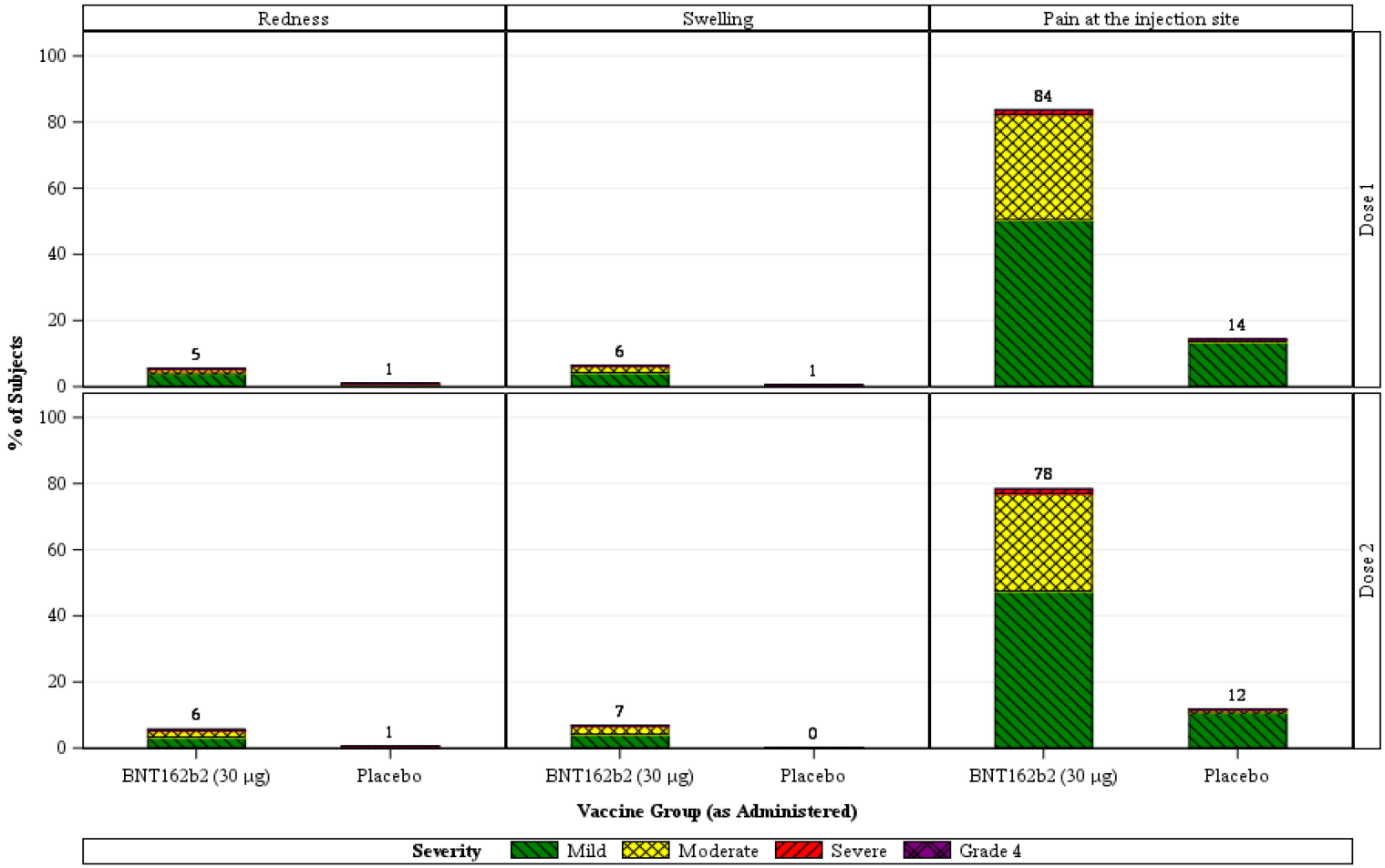
Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population
Age Group: 16-55 Years



Note: Number above each bar denotes percentage of subjects reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:24)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_CBER_EDIARY/adce_f001_lr_max_age_p3

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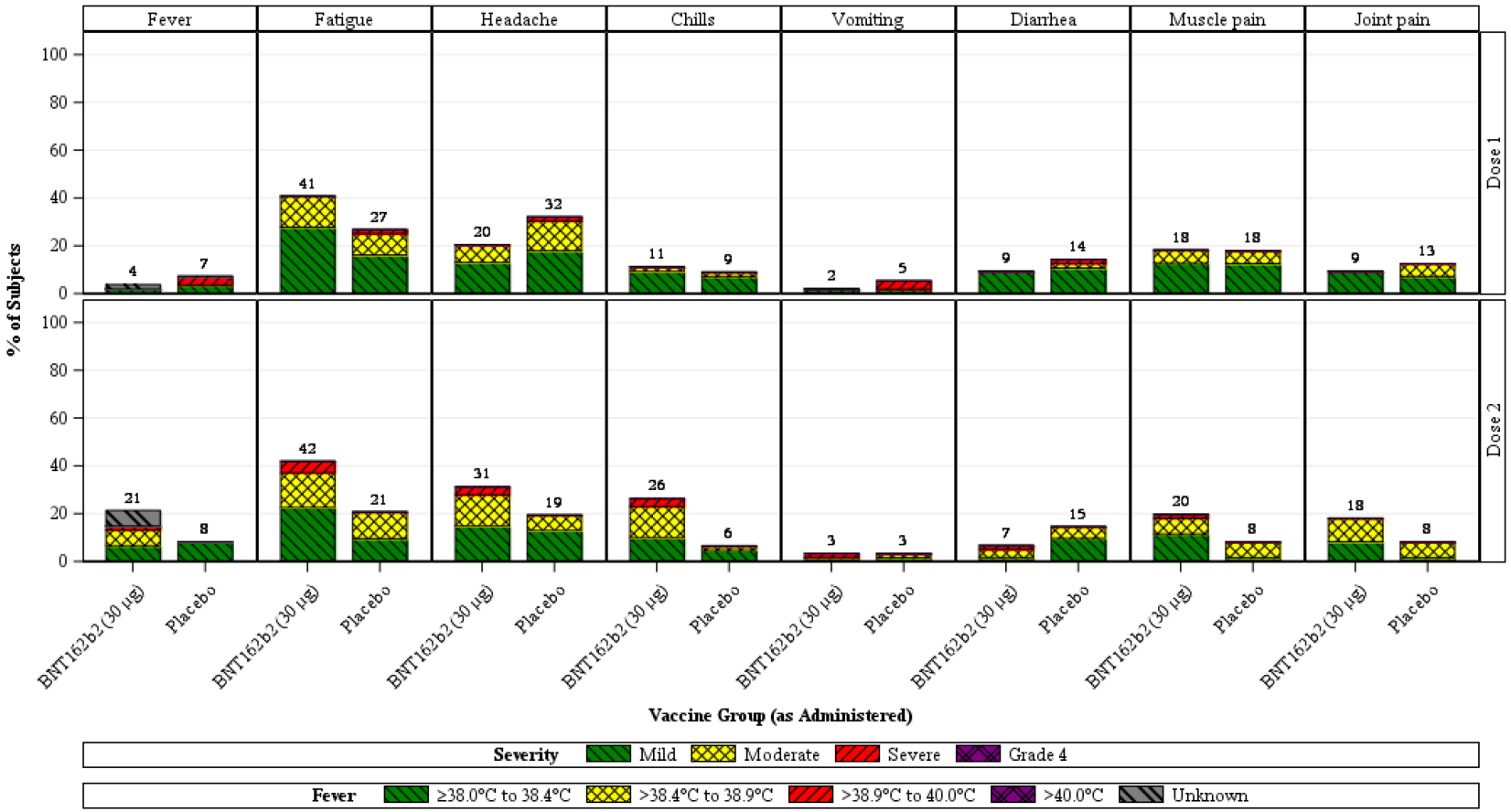
Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) –
Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population



Abbreviation: HIV = human immunodeficiency virus.

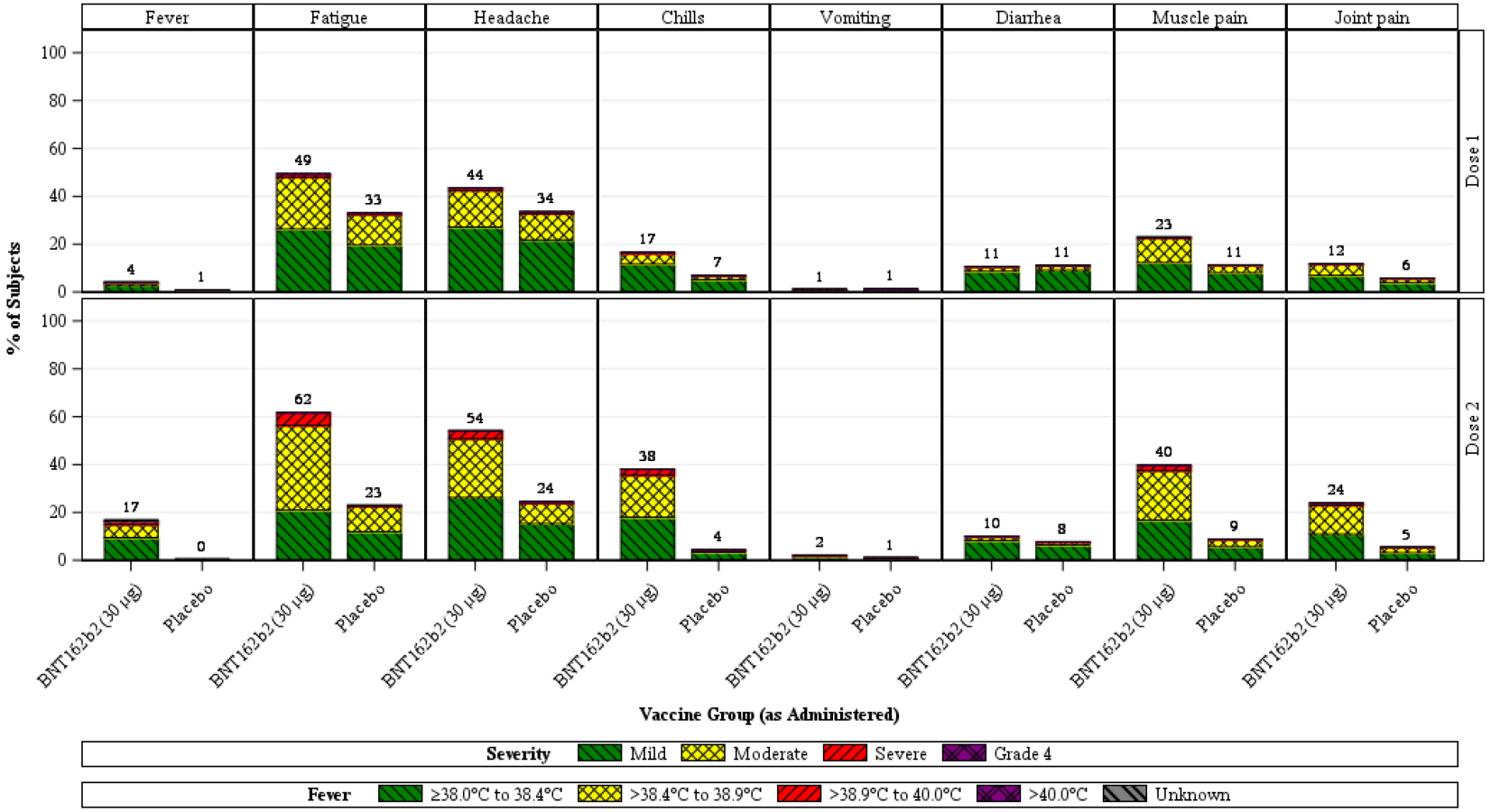
Note: Number above each bar denotes percentage of subjects reporting the event with any severity.

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 (22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:24)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_CBER_EDIARY/adce_f001_se_max_hiv_p3

090177e196f19a09\Final\Final On: 04-May-2021 06:41 (GMT)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) –
Phase 2/3 Subjects ≥16 Years of Age – Safety Population
Age Group: 16-55 Years



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 (22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:24)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_CBER_EDIARY/adce_f001_se_max_age_p3