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] (%)**
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)

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] (%)**
All 7 days[e]	2718 (54.8)	2481 (50.3)

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 ~~period (~~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 (~~25MAR2021 (19:~~22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:24~~27MAR2021 (01:55~~)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_CBER_EDIARY~~BLA~~/adce_s200_trns_p3_saf

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	158156 (5.54)	(4.76, 6.3)	2908	3028 (1.0)	(0.76, 1.54)
		Mild	2899	115 (4.0113 (3.9)	(3.32, 4.7)	2908	2119 (0.7)	(0.4, 1.10)
		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	185184 (6.43)	(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	5554 (1.9)	(1.4, 2.54)	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	29002899	24282426 (83.7)	(82.3, 85.10)	2908	418414 (14.42)	(13.10, 15.76)
		Mild	29002899	1464 (50.5)	(48.67, 52.3)	2908	395391 (13.64)	(12.42, 14.97)
		Moderate	29002899	924923 (31.98)	(30.21, 33.6)	2908	20 (0.7)	(0.4, 1.1)
		Severe	29002899	4039 (1.43)	(1.0, 1.98)	2908	3 (0.1)	(0.0, 0.3)
		Grade 4	29002899	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		Any local reaction[f]	29002899	24462444 (84.3)	(83.082.9, 85.6)	2908	438 (15.1432 (14.9)	(13.86, 16.42)
	2	Redness[d]						
		Any	26832682	152151 (5.76)	(4.8, 6.6)	2684	18 (0.7)	(0.4, 1.1)

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])
		Mild	2683~~2682~~	90 (3.4)	(2.7, 4.1)	2684	12 (0.4)	(0.2, 0.8)
		Moderate	2683~~2682~~	51~~50~~ (1.9)	(1.4, 2.5)	2684	6 (0.2)	(0.1, 0.5)
		Severe	2683~~2682~~	11 (0.4)	(0.2, 0.7)	2684	0	(0.0, 0.1)
		Grade 4	2683~~2682~~	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Swelling[d]						
		Any	2683~~2682~~	185~~183~~ (6.9~~8~~)	(6.0~~5.9~~, 7.9~~8~~)	2684	5 (0.2)	(0.1, 0.4)
		Mild	2683~~2682~~	112~~110~~ (4.2~~1~~)	(3.4, 5.0~~4.9~~)	2684	3 (0.1)	(0.0, 0.3)
		Moderate	2683~~2682~~	66 (2.5)	(1.9, 3.1)	2684	2 (0.1)	(0.0, 0.3)
		Severe	2683~~2682~~	7 (0.3)	(0.1, 0.5)	2684	0	(0.0, 0.1)
		Grade 4	2683~~2682~~	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Pain at the injection site[e]						
		Any	2691~~2682~~	2110~~2101~~ (78.4~~3~~)	(76.8, 80.0~~7, 79.9~~)	2684	315~~312~~ (11.7~~6~~)	(10.5, 13.0~~4, 12.9~~)
		Mild	2691~~2682~~	1280~~1274~~ (47.6~~5~~)	(45.7~~6~~, 49.5~~4~~)	2684	287~~284~~ (10.7~~6~~)	(9.5~~4~~, 11.9~~8~~)
		Moderate	2691~~2682~~	791~~788~~ (29.4)	(27.7, 31.2~~1~~)	2684	28 (1.0)	(0.7, 1.5)
		Severe	2691~~2682~~	39 (1.4~~5~~)	(1.0, 2.0)	2684	0	(0.0, 0.1)
		Grade 4	2691~~2682~~	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Any local reaction[f]	2691~~2682~~	2117~~2108~~ (78.7~~6~~)	(77.1~~0~~, 80.2~~1~~)	2684	328~~325~~ (12.2~~1~~)	(11.0~~10.9~~, 13.5~~4~~)
	Any dose	Redness[d]						
		Any	2909	278~~276~~ (9.6~~5~~)	(8.5~~4~~, 10.7~~6~~)	2921	44~~42~~ (1.5~~4~~)	(1.~~0,~~ 1, 2.0~~9~~)
		Mild	2909	181~~180~~ (6.2)	(5.4~~3~~, 7.2~~1~~)	2921	29 (1.~~27 (~~0~~.9~~)	(0.7~~6~~, 1.4~~3~~)
		Moderate	2909	79~~78~~ (2.7)	(2.2~~1~~, 3.4~~3~~)	2921	12 (0.4)	(0.2, 0.7)

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	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)
		Swelling[d]						
		Any	2909	312309 (10.76)	(9.65, 11.98)	2921	20 (0.7)	(0.4, 1.1)
		Mild	2909	197195 (6.87)	(5.98, 7.7)	2921	9 (0.3)	(0.1, 0.6)
		Moderate	2909	102101 (3.5)	(2.98, 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	25792577 (88.76)	(87.4, 89.87)	2921	590585 (20.20)	(18.86, 21.75)
		Mild	2909	12791280 (44.0)	(42.2, 45.8)	2921	543538 (18.64)	(17.2, 20.0, 19.9)
		Moderate	2909	12251223 (42.10)	(40.32, 43.9)	2921	44 (1.5)	(1.1, 2.0)
		Severe	2909	7574 (2.65)	(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	25922590 (89.10)	(87.98, 90.21)	2921	615 (21.1609 (20.8)	(19.64, 22.64)
>55 Years	1	Redness[d]						
		Any	2008	109106 (5.43)	(4.53, 6.53)	1989	2120 (1.10)	(0.76, 1.65)
		Mild	2008	7471 (3.75)	(2.98, 4.64)	1989	1413 (0.7)	(0.43, 1.21)
		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]						

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	2008	142141 (7.10)	(6.05.9, 8.32)	1989	2523 (1.32)	(0.87, 1.87)
		Mild	2008	8887 (4.43)	(3.5, 5.43)	1989	1311 (0.76)	(0.3, 1.10)
		Moderate	2008	52 (2.6)	(1.9, 3.4)	1989	12 (0.6)	(0.3, 1.1)
		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	14091408 (70.21)	(68.1, 72.21)	1989	187185 (9.43)	(8.21, 10.87)
		Mild	2008	11091108 (55.2)	(53.0, 57.4)	1989	179 (177 (8.9.0)	(7.87, 10.32)
		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	14351433 (71.54)	(69.43, 73.43)	1989	210207 (10.64)	(9.2, 12.01, 11.8)
	2	Redness[d]						
		Any	1860	134133 (7.2)	(6.10, 8.54)	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	5958 (3.21)	(2.4, 4.10)	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)

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	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]						
		Any	1863~~1860~~	123~~61230~~ (66.3~~1~~)	(64.1~~63.9~~, 68.5~~3~~)	183~~51833~~	147 (~~143 (7~~.8.0)	(6.8~~6~~, 9.3~~1~~)
		Mild	1863~~1860~~	879 (47.2~~873 (46.9~~)	(44.9~~6~~, 49.5~~2~~)	183~~51833~~	142~~138~~ (7.7~~5~~)	(6.6, 9.1~~4, 8.8~~)
		Moderate	1863~~1860~~	347 (18.6~~7~~)	(16.9, 20.5)	183~~51833~~	5 (0.3)	(0.1, 0.6)
		Severe	1863~~1860~~	10 (0.5)	(0.3, 1.0)	183~~51833~~	0	(0.0, 0.2)
		Grade 4	1863~~1860~~	0	(0.0, 0.2)	183~~51833~~	0	(0.0, 0.2)
		Any local reaction[f]	1863~~1860~~	1248 (67.0~~1243 (66.8~~)	(64.8~~6~~, 69.1~~0~~)	183~~51833~~	162~~158~~ (8.8~~6~~)	(7.6~~4~~, 10.2~~0~~)
	Any dose	Redness[d]						
		Any	2015	213~~210~~ (10.6~~4~~)	(9.3, 12.0~~1, 11.8~~)	1994	31~~30~~ (1.6~~5~~)	(1.1~~0~~, 2.2~~1~~)
		Mild	2015	122~~120~~ (6.1~~0~~)	(5.1~~0~~, 7.2~~1~~)	1994	21~~20~~ (1.1~~0~~)	(0.7~~6~~, 1.6~~5~~)
		Moderate	2015	76~~75~~ (3.8~~7~~)	(3.0~~2.9~~, 4.7~~6~~)	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~~237~~ (11.8)	(10.4, 13.3~~2~~)	1994	33~~31~~ (1.7~~6~~)	(1.1, 2.3~~2~~)
		Mild	2015	135~~134~~ (6.7)	(5.6, 7.9~~8~~)	1994	14~~12~~ (0.7~~6~~)	(0.4~~3~~, 1.2~~0~~)
		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)

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])
		Pain at the injection site[e]						
		Any	2015	15791576 (78.42)	(76.53, 80.10)	1994	269264 (13.52)	(12.0, 15.111.8, 14.8)
		Mild	2015	10791076 (53.54)	(51.32, 55.76)	1994	256251 (12.86)	(11.42, 14.41)
		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)
		Grade 4	2015	0	(0.0, 0.2)	1994	0	(0.0, 0.2)
		Any local reaction[f]	2015	15991597 (79.43)	(77.54, 81.10)	1994	300 (15.0294 (14.7)	(13.52, 16.74)

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 (25MAR2021 (19:22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:2427MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 sBLA CBER EDIARYBLA/adce s010 lr p3 saf

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	5554	2 (3 (5.5.7)	(1.1, 15.10.5, 12.7)	56	3 (5.4)	(1.1, 14.9)
	Mild	5554	2 (3 (5.5.7)	(1.1, 15.10.5, 12.7)	56	1 (1.8)	(0.0, 9.6)
	Moderate	5554	0	(0.0, 6.56)	56	0	(0.0, 6.4)
	Severe	5554	0	(0.0, 6.56)	56	2 (3.6)	(0.4, 12.3)
	Grade 4	5554	0	(0.0, 6.56)	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	5754	38 (66.734 (63.0)	(52.9, 78.648.7, 75.7)	56	9 (16.1)	(7.6, 28.3)
	Mild	5754	30 (52.626 (48.1)	(39.0, 66.034.3, 62.2)	56	8 (14.3)	(6.4, 26.2)
	Moderate	5754	8 (14.08)	(6.3, 25.86, 27.1)	56	1 (1.8)	(0.0, 9.6)
	Severe	5754	0	(0.0, 6.36)	56	0	(0.0, 6.4)
	Grade 4	5754	0	(0.0, 6.36)	56	0	(0.0, 6.4)
	Any local reaction[f]	5754	39 (68.435 (64.8)	(54.8, 80.150.6, 77.3)	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)

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])
	Mild	60	3 (5.0)	(1.0, 13.9)	62	1 (1.6)	(0.0, 8.7)
	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	6160	33 (54.132 (53.3)	(40.80, 66.93)	62	5 (8.1)	(2.7, 17.8)
	Mild	6160	23 (3722 (36.7)	(2524.6, 51.050.1)	62	5 (8.1)	(2.7, 17.8)
	Moderate	6160	9 (14.815.0)	(7.01, 26.26)	62	0	(0.0, 5.8)
	Severe	6160	1 (1.67)	(0.0, 8.89)	62	0	(0.0, 5.8)
	Grade 4	6160	0	(0.0, 5.96.0)	62	0	(0.0, 5.8)
	Any local reaction[f]	6160	33 (54.132 (53.3)	(40.80, 66.93)	62	5 (8.1)	(2.7, 17.8)
Any dose	Redness[d]						
	Any	7372	5 (6 (8.2.9)	(2.3.1, 17.0, 15.5)	74	3 (4.1)	(0.8, 11.4)
	Mild	7372	4 (5 (.6.8)	(2.3, 15.31.5, 13.6)	74	1 (1.4)	(0.0, 7.3)
	Moderate	7372	1 (1.4)	(0.0, 7.45)	74	0	(0.0, 4.9)
	Severe	7372	0	(0.0, 4.95.0)	74	2 (2.7)	(0.3, 9.4)
	Grade 4	7372	0	(0.0, 4.95.0)	74	0	(0.0, 4.9)

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	7472	54 (73.049 (68.1)	(61.4, 8256.0, 78.6)	74	12 (16.2)	(8.7, 26.6)
	Mild	7472	40 (54.135 (48.6)	(42.1, 6536.7, 60.7)	74	11 (14.9)	(7.7, 25.0)
	Moderate	7472	13 (17.618.1)	(9.710.0, 28.29)	74	1 (1.4)	(0.0, 7.3)
	Severe	7472	1 (1.4)	(0.0, 7.35)	74	0	(0.0, 4.9)
	Grade 4	7472	0	(0.0, 4.95.0)	74	0	(0.0, 4.9)
	Any local reaction[f]	7472	54 (73.049 (68.1)	(61.4, 8256.0, 78.6)	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 (25MAR2021 (19:22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:2427MAR2021 (01:55)

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])

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 sBLA CBER EDIARY~~BLA~~/adce s010 lr hiv p3 saf

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)

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])
		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)
		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)

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])**
		Pain at the injection site[e]						
		Any	154~~153~~	94 (61.0~~93 (60.8~~)	(52.96, 68.86)	165	11 (6.7)	(3.4, 11.6)
		Mild	154~~153~~	54 (35.1~~53 (34.6~~)	(27.6, 43.2~~1, 42.7~~)	165	9 (5.5)	(2.5, 10.1)
		Moderate	154~~153~~	34 (22.12)	(15.89, 29.56)	165	2 (1.2)	(0.1, 4.3)
		Severe	154~~153~~	6 (3.9)	(1.45, 8.3)	165	0	(0.0, 2.2)
		Grade 4	154~~153~~	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		Any local reaction[f]	154~~153~~	96~~95~~ (62.31)	(54.2, 70.0~~53.9, 69.8~~)	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)
		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)

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])**
		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~~250~~ (5.4~~3~~)	(4.8~~7~~, 6.1~~0~~)	4690	46 (1.4~~3~~ (0.~~9~~)	(0.7, 1.3~~2~~)
		Mild	4701	183~~178~~ (3.9~~8~~)	(3.3~~,~~ 4, ~~.~~4.5)	4690	33~~30~~ (0.7~~6~~)	(0.5, 1.4~~,~~ 0.~~9~~)
		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~~308~~ (6.6)	(5.9, 7.3)	4690	40~~38~~ (0.9~~8~~)	(0.6, 1.2~~1~~)
		Mild	4701	204~~203~~ (4.3)	(3.8, 5.0~~4.9~~)	4690	19~~17~~ (0.4)	(0.2, 0.6)
		Moderate	4701	99~~98~~ (2.1)	(1.7, 2.6~~5~~)	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)

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])**
		Pain at the injection site[e]						
		Any	47024~~4701~~	36853~~3682~~ (78.43)	(77.21, 79.5)	4690	579~~573~~ (12.32)	(11.43, 13.32)
		Mild	47024~~4701~~	24872~~2486~~ (52.9)	(51.54, 54.3)	4690	552~~546~~ (11.86)	(10.97, 12.76)
		Moderate	47024~~4701~~	11591~~1158~~ (24.6)	(23.4, 25.9)	4690	25 (0.5)	(0.3, 0.8)
		Severe	47024~~4701~~	39~~38~~ (0.8)	(0.6, 1.1)	4690	2 (0.0)	(0.0, 0.2)
		Grade 4	47024~~4701~~	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Any local reaction[f]	47024~~4701~~	37253~~3721~~ (79.2)	(78.0, 80.43)	4690	620~~611~~ (13.20)	(12.31, 14.20)
	2	Redness[d]						
		Any	43694~~4368~~	279~~277~~ (6.43)	(5.6, 7, 7.2.1)	4334	31 (0.7)	(0.5, 1.0)
		Mild	43694~~4368~~	149 (3.4)	(2.9, 4.0)	4334	22 (0.5)	(0.3, 0.8)
		Moderate	43694~~4368~~	109~~107~~ (2.54)	(2.10, 3.0)	4334	9 (0.2)	(0.1, 0.4)
		Severe	43694~~4368~~	21 (0.5)	(0.3, 0.7)	4334	0	(0.0, 0.1)
		Grade 4	43694~~4368~~	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Swelling[d]						
		Any	43694~~4368~~	320~~318~~ (7.3)	(6.65, 8.1)	4334	17 (0.4)	(0.2, 0.6)
		Mild	43694~~4368~~	187~~185~~ (4.32)	(3.7, 4.9)	4334	7 (0.2)	(0.1, 0.3)
		Moderate	43694~~4368~~	122 (2.8)	(2.3, 3.3)	4334	9 (0.2)	(0.1, 0.4)
		Severe	43694~~4368~~	11 (0.3)	(0.1, 0.5)	4334	1 (0.0)	(0.0, 0.1)
		Grade 4	43694~~4368~~	0	(0.0, 0.1)	4334	0	(0.0, 0.1)

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])
		Pain at the injection site[e]						
		Any	4379~~4368~~	3238~~3224~~ (73.9~~8~~)	(72.6~~5~~, 75.2~~1~~)	4336~~4334~~	450~~443~~ (10.4~~2~~)	(9.5~~3~~, 11.3~~2~~)
		Mild	4379~~4368~~	2096~~2085~~ (47.9~~7~~)	(46.4~~2~~, 49.4~~2~~)	4336~~4334~~	419~~412~~ (9.7~~5~~)	(8.8~~6~~, 10.6~~4~~)
		Moderate	4379~~4368~~	1099~~1096~~ (25.1)	(23.8, 26.4)	4336~~4334~~	31 (0.7)	(0.5, 1.0)
		Severe	4379~~4368~~	43 (1.0)	(0.7, 1.3)	4336~~4334~~	0	(0.0, 0.1)
		Grade 4	4379~~4368~~	0	(0.0, 0.1)	4336~~4334~~	0	(0.0, 0.1)
		Any local reaction[f]	4379~~4368~~	3255~~3242~~ (74.3~~2~~)	(73.0~~72.9~~, 75.6~~5~~)	4336~~4334~~	477 (11.0~~470 (10.8~~)	(10.1, 12.0~~9.9, 11.8~~)
	Any dose	Redness[d]						
		Any	4718	472 (10.0~~467 (9.9~~)	(9.2~~1~~, 10.9~~8~~)	4708	70~~67~~ (1.5~~4~~)	(1.2, 1.9~~, 1.8~~)
		Mild	4718	291~~288~~ (6.2~~1~~)	(5.5~~4~~, 6.9~~8~~)	4708	48~~45~~ (1.0)	(0.8~~7~~, 1.3)
		Moderate	4718	150~~148~~ (3.2~~1~~)	(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~~523~~ (11.2~~1~~)	(10.3~~2~~, 12.1~~0~~)	4708	51~~49~~ (1.1~~0~~)	(0.8, 1.4)
		Mild	4718	321~~318~~ (6.8~~7~~)	(6.1~~0~~, 7.6~~5~~)	4708	22~~20~~ (0.5~~4~~)	(0.3, 0.7)
		Moderate	4718	188~~187~~ (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)

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])
		Pain at the injection site[e]						
		Any	4718	39923987 (84.65)	(83.64, 85.65)	4708	826816 (17.53)	(16.53, 18.74)
		Mild	4718	22752273 (48.2)	(46.87, 49.76)	4708	772762 (16.42)	(15.41, 17.53)
		Moderate	4718	16391637 (34.7)	(33.43, 36.1)	4708	52 (1.1)	(0.8, 1.4)
		Severe	4718	7877 (1.76)	(1.3, 2.10)	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	40224018 (85.2)	(84.21, 86.2)	4708	880868 (18.74)	(17.63, 19.86)

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 (25MAR2021 (19:22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:2427MAR2021 (01:55)

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])

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 sBLA CBER EDIARY~~BLA~~/adce s010 lr base p3 saf

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~~156~~	30~~28~~
		Mean (SD)	2.3~~2~~ (1.99~~92~~)	1.7 (1.35~~39~~)
		Median	1.5~~0~~	1.0
		Min, max	(1, 14)	(1, 6)
		Swelling		
		n[a]	185~~184~~	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]	242~~824~~26	418~~414~~
		Mean (SD)	2.2 (1.49)	1.5~~6~~ (1.50~~51~~)
		Median	2.0	1.0
		Min, max	(1, 22)	(1, 17)
		Unknown[b]	2	1
	2	Redness		
		n[a]	152~~151~~	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~~183~~	5

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 (1.4950)	2.2 (0.84)
		Median	2.0	2.0
		Min, max	(1, 8)	(1, 3)
		Pain at the injection site		
		n[a]	21102101	315312
		Mean (SD)	2.5 (2.2021)	1.9 (2.8284)
		Median	2.0	1.0
		Min, max	(1, 70)	(1, 35)
		Unknown[b]	5	0
>55 Years	1	Redness		
		n[a]	109106	2120
		Mean (SD)	2.43 (2.3633)	1.9 (2.0610)
		Median	2.0	1.0
		Min, max	(1, 20)	(1, 10)
		Swelling		
		n[a]	142141	2523
		Mean (SD)	1.78 (1.0304)	2.86 (2.8450)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 11)
		Pain at the injection site		
		n[a]	14091408	187185
		Mean (SD)	1.9 (1.46)	1.8 (2.1516)
		Median	2.0	1.0
		Min, max	(1, 22)	(1, 19)

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~~133~~	14
		Mean (SD)	3.0 (3.91~~92~~)	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~~30~~)
		Median	2.0	1.0
		Min, max	(1, 34)	(1, 5)
		Pain at the injection site		
		n[a]	1236~~1230~~	147~~143~~
		Mean (SD)	2.4 (1.98~~99~~)	1.9 (2.65~~7 (1.25~~)
		Median	2.0	1.0
		Min, max	(1, 36)	(1, 30~~7~~)
		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~~25MAR2021 (19:19~~) Source Data: adcevd Table Generation: 29APR2021 (23:34~~27MAR2021 (01:29~~)

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**

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_CBER_EDIARY~~BLA~~/adce_s030_lr_dur_p3_saf

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]	32	3
	Mean (SD)	1.75 (0.5871)	1.0 (0.00)
	Median	2.01.5	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]	3834	9
	Mean (SD)	2.0 (1.1421)	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

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**
	Mean (SD)	1.8 (0.84)	NE (NE)
	Median	2.0	NE
	Min, max	(1, 3)	(NE, NE)
	Pain at the injection site		
	n[a]	3332	5
	Mean (SD)	1.98 (1.1704)	2.0 (1.41)
	Median	1.0	1.0
	Min, max	(1, 54)	(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 (22:0625MAR2021 (19:19) Source Data: adcevd Table Generation: 29APR2021 (23:3427MAR2021 (01:29)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 sBLA CBER EDIARYBLA/adce s030 lr dur hiv p3 saf

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~~156~~	30~~28~~
		Mean (SD)	2.3 (0.98)	1.~~8~~9 (1.27~~30~~)
		Median	2.0	1.0
		Min, max	(1, 7)	(1, 5)
		Swelling		
		n[a]	185~~184~~	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~~2426~~	418~~414~~
		Mean (SD)	1.4 (0.55)	1.6 (1.15~~16~~)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 7)
		Any local reaction[b]		
		n[a]	2446~~2444~~	438~~432~~
		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~~151~~	18
		Mean (SD)	2.5 (0.98~~97~~)	2.2 (1.50)

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~~183~~	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~~2101~~	315~~312~~
		Mean (SD)	1.4 (0.59)	1.~~45~~ (0.95~~96~~)
		Median	1.0	1.0
		Min, max	(1, 6)	(1, 7)
		Any local reaction[b]		
		n[a]	2117~~2108~~	328~~325~~
		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~~106~~	21~~20~~
		Mean (SD)	2.3 (0.82~~81~~)	1.6 (0.51~~50~~)
		Median	2.0	2.0
		Min, max	(1, 5)	(1, 2)
		Swelling		

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~~141~~	25~~23~~
		Mean (SD)	1.9 (0.58~~57~~)	1.5~~4~~ (0.87~~73~~)
		Median	2.0	1.0
		Min, max	(1, 4)	(1, 4)
		Pain at the injection site		
		n[a]	1409~~1408~~	187~~185~~
		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~~1433~~	210~~207~~
		Mean (SD)	1.6 (0.53)	1.8 (1.14~~15~~)
		Median	2.0	1.0
		Min, max	(1, 5)	(1, 7)
	2	Redness		
		n[a]	134~~133~~	14
		Mean (SD)	2.~~78~~ (1.04~~03~~)	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)

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

Age Group	Dose	Local Reaction	Vaccine Group (as Administered) BNT162b2 (30 µg)	Vaccine Group (as Administered) Placebo
		Pain at the injection site		
		n[a]	12361230	147143
		Mean (SD)	1.56 (0.68)	1.7 (1.1819)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 7)
		Any local reaction[b]		
		n[a]	12481243	162158
		Mean (SD)	1.56 (0.6667)	1.7 (1.2122)
		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 (25MAR2021 (19:22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:2227MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2_unblinded/C4591001_sBLA_CBER_EDIARYBLA/adce_s050_lr_onset_p3_saf

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]	32	3
	Mean (SD)	1.7 (2.0.58 (0.00)	1.0 (0.00)
	Median	2.0	1.0
	Min, max	(12, 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]	3834	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]	3935	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)

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]	3332	5
	Mean (SD)	1.56 (0.67)	1.6 (0.89)
	Median	1.05	1.0
	Min, max	(1, 3)	(1, 3)
	Any local reaction[b]		
	n[a]	3332	5
	Mean (SD)	1.56 (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 (25MAR2021 (19:22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:2227MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 sBLA CBER EDIARYBLA/adce s050 lr onset hiv p3 saf

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						
		~~≥38.0°C~~Any	2899	~~119~~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~~[d]Fatigue[e]						
		Any	~~2899~~2900	~~1431~~1433 (49.4)	(47.~~5~~6, 51.~~2~~3)	2908	960 (33.0)	(31.3, 34.8)
		Mild	~~2899~~2900	~~760~~762 (26.~~2~~3)	(24.~~6~~7, 27.9)	2908	570 (19.6)	(18.2, 21.1)
		Moderate	~~2899~~2900	630 (21.7)	(20.2, 23.3)	2908	372 (12.8)	(11.6, 14.1)
		Severe	~~2899~~2900	41 (1.4)	(1.0, 1.9)	2908	18 (0.6)	(0.4, 1.0)
		Grade 4	~~2899~~2900	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		~~Headache~~[d]Headache[e]						
		Any	~~2899~~2901	~~1262~~1264 (43.~~5~~6)	(41.~~7~~8, 45.4)	~~2908~~2909	~~975~~976 (33.~~5~~6)	(31.8, 35.3)
		Mild	~~2899~~2901	~~785~~787 (27.1)	(25.5, 28.~~7~~8)	~~2908~~2909	633 (21.8)	(20.3, 23.3)
		Moderate	~~2899~~2901	444 (15.3)	(14.0, 16.7)	~~2908~~2909	~~318 (10.9~~319 (11.0)	(9.~~8~~9, 12.~~1~~2)

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	~~2899~~2901	33 (1.1)	(0.8, 1.6)	~~2908~~2909	24 (0.8)	(0.5, 1.2)
		Grade 4	~~2899~~2901	0	(0.0, 0.1)	~~2908~~2909	0	(0.0, 0.1)
		~~Chills~~[d]Chills[e]						
		Any	~~2899~~2900	~~479~~481 (16.~~5~~6)	(15.2, ~~17.9~~18.0)	2908	~~199~~200 (6.~~8~~9)	(6.0, 7.~~8~~9)
		Mild	~~2899~~2900	338 (11.7)	(10.5, 12.9)	2908	~~148~~149 (5.1)	(4.~~3~~4, 6.0)
		Moderate	~~2899~~2900	~~126~~128 (4.~~3~~4)	(3.~~6~~7, 5.2)	2908	49 (1.7)	(1.2, 2.2)
		Severe	~~2899~~2900	15 (0.5)	(0.3, 0.9)	2908	2 (0.1)	(0.0, 0.2)
		Grade 4	~~2899~~2900	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		~~Vomiting~~[e]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~~[f]Diarrhea[g]						
		Any	2899	309 (10.7)	(9.6, 11.8)	2908	~~323~~324 (11.1)	(10.0, 12.3)
		Mild	2899	251 (8.7)	(7.7, 9.7)	2908	~~264~~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~~[d]pain[e]						

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])
		Any	~~2899~~2900	~~664 (22.9~~667 (23.0)	(21.~~4~~5, 24.~~5~~6)	2908	329 (11.3)	(10.2, 12.5)
		Mild	~~2899~~2900	~~353~~355 (12.2)	(11.~~0~~1, 13.~~4~~5)	2908	231 (7.9)	(7.0, 9.0)
		Moderate	~~2899~~2900	~~296~~297 (10.2)	(9.~~1~~2, 11.4)	2908	96 (3.3)	(2.7, 4.0)
		Severe	~~2899~~2900	15 (0.5)	(0.3, 0.9)	2908	2 (0.1)	(0.0, 0.2)
		Grade 4	~~2899~~2900	0	(0.0, 0.1)	2908	0	(0.0, 0.1)
		New or worsened joint ~~pain[d]~~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)
		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[g]~~event[h]	~~2899~~2901	~~1979~~1983 (68.~~3~~4)	(66.~~5~~6, 70.0)	~~2908~~2909	~~1559~~1560 (53.6)	(51.8, 55.~~4~~5)
		Use of antipyretic or pain ~~medication[h]~~medication[i]	2899	805 (27.8)	(26.1, 29.4)	2908	398 (13.7)	(12.5, 15.0)
	2	Fever						
		~~≥38.0°C~~Any	~~2682~~2691	~~440~~456 (16.~~4~~9)	(15.~~0, 17.9~~5, 18.4)	~~2684~~2685	~~11~~13 (0.~~4~~5)	(0.~~2~~3, 0.~~7~~8)
		≥38.0°C to 38.4°C	~~2682~~2691	254 (9.~~5~~4)	(8.4, 10.6)	~~2684~~2685	5 (0.2)	(0.1, 0.4)
		>38.4°C to 38.9°C	~~2682~~2691	146 (5.4)	(4.6, 6.~~4~~3)	~~2684~~2685	4 (0.1)	(0.0, 0.4)
		>38.9°C to 40.0°C	~~2682~~2691	39 (1.~~5~~4)	(1.0, 2.0)	~~2684~~2685	2 (0.1)	(0.0, 0.3)

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	~~2682~~2691	1 (0.0)	(0.0, 0.2)	~~2684~~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[d]~~Fatigue[e]						
		Any	~~2682~~2690	~~1649~~1659 (61.~~5~~7)	(59.~~6~~8, 63.~~3~~5)	2684	~~614 (22.9~~617 (23.0)	(21.~~3~~4, 24.~~5~~6)
		Mild	~~2682~~2690	~~558~~563 (20.~~8~~9)	(19.~~3~~4, 22.~~4~~5)	2684	~~317~~320 (11.~~8~~9)	(10.~~6~~7, 13.~~1~~2)
		Moderate	~~2682~~2690	~~949~~952 (35.4)	(33.6, 37.2)	2684	283 (10.5)	(9.4, 11.8)
		Severe	~~2682~~2690	~~142~~144 (5.~~3~~4)	(4.5, 6.~~2~~3)	2684	14 (0.5)	(0.3, 0.9)
		Grade 4	~~2682~~2690	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		~~Headache[d]~~ Headache[e]						
-	-	Any	~~2682~~2688	~~1448 (54.0)~~ 1456 (54.2)	~~(52.1, 55.9)~~ (52.3, 56.1)	~~2684~~2686	~~652 (24.3)~~ 657 (24.5)	~~(22.7, 26.0)~~ (22.8, 26.1)
-	-	Mild	~~2682~~2688	~~699 (26.1)~~ 704 (26.2)	~~(24.4, 27.8)~~ (24.5, 27.9)	~~2684~~2686	~~404 (15.1)~~ 409 (15.2)	~~(13.7, 16.5)~~ (13.9, 16.6)
-	-	Moderate	~~2682~~2688	~~658 (24.5)~~ 660 (24.6)	~~(22.9, 26.2)~~ (22.9, 26.2)	~~2684~~2686	230 (8.6)	(7.5, 9.7)
-	-	Severe	~~2682~~2688	~~91 (3.4)~~ 92 (3.4)	~~(2.7, 4.1)~~ (2.8, 4.2)	~~2684~~2686	18 (0.7)	(0.4, 1.1)
-	-	Grade 4	~~2682~~2688	0	~~(0.0, 0.1)~~	~~2684~~2686	0	(0.0, 0.1)
-	-	~~Chills[d]~~ Chills[e]	-	-	-	-	-	-
-	-	Any	~~2682~~2688	~~1015 (37.8)~~ 1024 (38.1)	~~(36.0, 39.7)~~	2684	~~114 (4.2)~~ 115 (4.3)	~~(3.5, 5.1)~~

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	~~2682~~2688	~~477 (17.8)~~ 482 (17.9)	~~(16.4, 19.3)~~	2684	~~89 (3.3)~~ 90 (3.4)	~~(2.7, 4.1)~~
~~-~~	~~-~~	Moderate	~~2682~~2688	~~469 (17.5)~~ 473 (17.6)	~~(16.1, 19.0)~~	2684	23 (0.9)	(0.5, 1.3)
~~-~~	~~-~~	Severe	~~2682~~2688	~~69 (2.6)~~ 69 (2.6)	~~(2.0, 3.2)~~	2684	2 (0.1)	(0.0, 0.3)
~~-~~	~~-~~	Grade 4	~~2682~~2688	~~0~~	~~(0.0, 0.1)~~	2684	0	(0.0, 0.1)
~~-~~	~~-~~	~~Vomiting~~[e] 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~~[f]Diarrhea[g]						
		Any	2682	269 (10.0)	(8.9, 11.2)	~~2684~~2685	~~205~~206 (7.~~6~~7)	(6.7, 8.7)
		Mild	2682	219 (8.2)	(7.2, 9.3)	~~2684~~2685	~~169~~170 (6.3)	(5.4, 7.3)
		Moderate	2682	44 (1.6)	(1.2, 2.2)	~~2684~~2685	35 (1.3)	(0.9, 1.8)
		Severe	2682	6 (0.2)	(0.1, 0.5)	~~2684~~2685	1 (0.0)	(0.0, 0.2)
		Grade 4	2682	0	(0.0, 0.1)	~~2684~~2685	0	(0.0, 0.1)
		New or worsened muscle ~~pain~~[d]pain[e]						
		Any	~~2682~~2692	~~1055~~1069 (39.~~3~~7)	(37.~~5~~9, 41.~~2~~6)	2684	237 (8.8)	(7.8, 10.0)

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	~~2682~~2692	~~441~~450 (16.~~4~~7)	(15.~~1, 17.9~~3, 18.2)	2684	150 (5.6)	(4.7, 6.5)
		Moderate	~~2682~~2692	~~552~~557 (20.~~6~~7)	(19.~~1~~2, 22.~~2~~3)	2684	84 (3.1)	(2.5, 3.9)
		Severe	~~2682~~2692	62 (2.3)	(1.8, ~~3.0~~2.9)	2684	3 (0.1)	(0.0, 0.3)
		Grade 4	~~2682~~2692	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		New or worsened joint ~~pain[d]~~pain[e]						
		Any	~~2682~~2684	~~638 (23.8~~643 (24.0)	(22.~~2~~4, 25.~~4~~6)	2684	147 (5.5)	(4.6, 6.4)
		Mild	~~2682~~2684	~~291~~293 (10.9)	(9.~~7~~8, 12.~~1~~2)	2684	82 (3.1)	(2.4, 3.8)
		Moderate	~~2682~~2684	~~320 (11.9~~323 (12.0)	(10.~~7~~8, 13.~~2~~3)	2684	61 (2.3)	(1.7, 2.9)
		Severe	~~2682~~2684	27 (1.0)	(0.7, 1.5)	2684	4 (0.1)	(0.0, 0.4)
		Grade 4	~~2682~~2684	0	(0.0, 0.1)	2684	0	(0.0, 0.1)
		Any systemic ~~event[g]~~event[h]	~~2682~~2702	~~2034 (75.8~~2057 (76.1)	(74.~~2~~5, 77.~~4~~7)	~~2684~~2687	~~1026~~1032 (38.~~2~~4)	(36.~~4~~6, 40.~~1~~3)
		Use of antipyretic or pain ~~medication[h]~~medication[i]	2682	1213 (45.2)	(43.3, 47.1)	2684	320 (11.9)	(10.7, 13.2)
	Any dose	Fever						
		~~≥38.0°C~~Any	2909	~~517 (17.8~~533 (18.3)	(16.~~4~~9, 19.~~2~~8)	~~2921~~2922	~~34~~36 (1.2)	(0.~~8~~9, 1.~~6~~7)
		≥38.0°C to 38.4°C	2909	310 (10.7)	(9.6, 11.8)	~~2921~~2922	20 (0.7)	(0.4, 1.1)

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])
		>38.4°C to 38.9°C	2909	163 (5.6)	(4.8, 6.5)	29212922	9 (0.3)	(0.1, 0.6)
		>38.9°C to 40.0°C	2909	43 (1.5)	(1.1, 2.0)	29212922	5 (0.2)	(0.1, 0.4)
		>40.0°C	2909	1 (0.0)	(0.0, 0.2)	29212922	0	(0.0, 0.1)
		Unknown[d]	2909	16 (0.6)	(0.3, 0.9)	2922	2 (0.1)	(0.0, 0.2)
		Fatigue[d]Fatigue[e]						
		Any	2909	20382042 (70.12)	(68.45, 71.79)	2921	1172 (40.1)	(38.3, 41.9)
		Mild	2909	672673 (23.1)	(21.6, 24.7)	2921	615 (21.1)	(19.6, 22.6)
		Moderate	2909	1191 (40.91192 (41.0)	(39.12, 42.8)	2921	529 (18.1)	(16.7, 19.6)
		Severe	2909	175177 (6.01)	(5.2, 6.97.0)	2921	28 (1.0)	(0.6, 1.4)
		Grade 4	2909	0	(0.0, 0.1)	2921	0	(0.0, 0.1)
		Headache[d]Headache[e]						
		Any	2909	1889 (64.91893 (65.1)	(63.23, 66.78)	29212922	1225 (41.91229 (42.1)	(40.13, 43.89)
		Mild	2909	870 (29.9873 (30.0)	(28.23, 31.67)	29212922	730733 (25.01)	(23.45, 26.67)
		Moderate	2909	901 (31.0)	(29.3, 32.7)	29212922	454455 (15.56)	(14.23, 16.9)
		Severe	2909	118119 (4.1)	(3.4, 4.89)	29212922	41 (1.4)	(1.0, 1.9)
		Grade 4	2909	0	(0.0, 0.1)	29212922	0	(0.0, 0.1)
		Chills[d]Chills[e]						
		Any	2909	12081215 (41.58)	(39.740.0, 43.36)	2921	270272 (9.23)	(8.23, 10.4)

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	2909	~~594~~598 (20.~~4~~6)	(19.~~0, 21.9~~1, 22.1)	2921	~~205~~207 (7.~~0~~1)	(6.~~1~~2, 8.~~0~~1)
		Moderate	2909	~~532~~535 (18.~~3~~4)	(~~16.9~~17.0, 19.~~7~~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~~[e]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~~[f]Diarrhea[g]						
		Any	2909	492 (16.9)	(15.6, 18.3)	2921	~~460~~462 (15.~~7~~8)	(14.~~4~~5, 17.~~1~~2)
		Mild	2909	393 (13.5)	(12.3, 14.8)	2921	~~369~~371 (12.~~6~~7)	(11.~~4, 13.9~~5, 14.0)
		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~~[d]pain[e]						
		Any	2909	~~1325~~1335 (45.~~5~~9)	(~~43.7~~44.1, 47.~~4~~7)	2921	471 (16.1)	(14.8, 17.5)
		Mild	2909	~~530~~534 (18.~~2~~4)	(~~16.8~~17.0, 19.~~7~~8)	2921	304 (10.4)	(9.3, 11.6)
		Moderate	2909	~~721 (24.8~~727 (25.0)	(23.~~2~~4, 26.~~4~~6)	2921	162 (5.5)	(4.7, 6.4)

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	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[d]~~pain[e]						
		Any	2909	~~799~~804 (27.~~5~~6)	(~~25.9~~26.0, 29.~~1~~3)	2921	272 (9.3)	(8.3, 10.4)
		Mild	2909	~~359~~361 (12.~~3~~4)	(11.2, 13.~~6~~7)	2921	161 (5.5)	(4.7, 6.4)
		Moderate	2909	~~408~~411 (14.~~0~~1)	(12.~~8~~9, 15.~~3~~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[g]~~event[h]	2909	~~2446~~2451 (84.~~1~~3)	(82.~~7~~9, 85.~~4~~6)	~~2921~~2922	~~1797~~1798 (61.5)	(59.7, 63.3)
		Use of antipyretic or pain ~~medication[h]~~medication[i]	2909	1485 (51.0)	(49.2, 52.9)	2921	605 (20.7)	(19.3, 22.2)
>55 Years	1	Fever						
		~~≥38.0°C~~Any	2008	~~26~~27 (1.3)	(0.~~8, 1.~~9, 2.0)	1989	~~8~~9 (0.~~4~~5)	(0.2, 0.~~8~~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)
		>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[d]~~ Fatigue[e]						

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])
		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[d]~~Headache[e]						
		Any	2008	503 (25.0)	(23.2, 27.0)	~~1989~~1990	~~363~~365 (18.3)	(16.~~6~~7, 20.~~0~~1)
		Mild	2008	381 (19.0)	(17.3, 20.8)	~~1989~~1990	~~267~~269 (13.~~4~~5)	(12.0, 15.~~0~~1)
		Moderate	2008	120 (6.0)	(5.0, 7.1)	~~1989~~1990	93 (4.7)	(3.8, 5.7)
		Severe	2008	2 (0.1)	(0.0, 0.4)	~~1989~~1990	3 (0.2)	(0.0, 0.4)
		Grade 4	2008	0	(0.0, 0.2)	~~1989~~1990	0	(0.0, 0.2)
		~~Chills[d]~~Chills[e]						
		Any	2008	~~130~~131 (6.5)	(5.~~4~~5, 7.~~6~~7)	1989	69 (3.5)	(2.7, 4.4)
		Mild	2008	~~102~~103 (5.1)	(4.2, 6.~~1~~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[e]~~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)
		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)

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])
		Grade 4	2008	0	(0.0, 0.2)	1989	0	(0.0, 0.2)
		~~Diarrhea~~[f]Diarrhea[g]						
		Any	2008	168 (8.4)	(7.2, 9.7)	~~1989~~1990	~~130~~131 (6.~~5~~6)	(5.5, 7.~~7~~8)
		Mild	2008	137 (6.8)	(5.8, 8.0)	~~1989~~1990	~~109~~110 (5.5)	(4.~~5~~6, 6.6)
		Moderate	2008	27 (1.3)	(0.9, 2.0)	~~1989~~1990	20 (1.0)	(0.6, 1.5)
		Severe	2008	4 (0.2)	(0.1, 0.5)	~~1989~~1990	1 (0.1)	(0.0, 0.3)
		Grade 4	2008	0	(0.0, 0.2)	~~1989~~1990	0	(0.0, 0.2)
		New or worsened muscle ~~pain~~[d]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~~[d]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)

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])
		Any systemic ~~event[g]~~event[h]	2008	~~984~~985 (49.~~01~~)	(46.8, 51.~~23~~)	~~1989~~1990	~~749~~751 (37.7)	(35.~~56~~, 39.~~89~~)
		Use of antipyretic or pain ~~medication[h]~~medication[i]	2008	382 (19.0)	(17.3, 20.8)	1989	224 (11.3)	(9.9, 12.7)
	2	Fever						
		~~≥38.0°C~~Any	~~1860~~1862	~~219 (11.8~~224 (12.0)	(10.~~36~~, 13.~~36~~)	1833	4 (0.2)	(0.1, 0.6)
		≥38.0°C to 38.4°C	~~1860~~1862	158 (8.5)	(7.3, 9.~~98~~)	1833	2 (0.1)	(0.0, 0.4)
		>38.4°C to 38.9°C	~~1860~~1862	54 (2.9)	(2.2, 3.8)	1833	1 (0.1)	(0.0, 0.3)
		>38.9°C to 40.0°C	~~1860~~1862	7 (0.4)	(0.2, 0.8)	1833	1 (0.1)	(0.0, 0.3)
		>40.0°C	~~1860~~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[d]~~Fatigue[e]						
		Any	~~1860~~1862	~~949~~952 (51.~~01~~)	(48.~~78~~, 53.~~34~~)	~~1833~~1834	~~306~~307 (16.7)	(15.~~01~~, 18.5)
		Mild	~~1860~~1862	~~391~~393 (21.~~01~~)	(19.~~2, 22.9~~3, 23.0)	~~1833~~1834	~~183~~184 (10.0)	(8.~~67~~, 11.~~45~~)
		Moderate	~~1860~~1862	~~497~~498 (26.7)	(24.7, 28.8)	~~1833~~1834	121 (6.6)	(5.5, 7.8)
		Severe	~~1860~~1862	60 (3.2)	(2.5, 4.1)	~~1833~~1834	2 (0.1)	(0.0, 0.4)
		Grade 4	~~1860~~1862	1 (0.1)	(0.0, 0.3)	~~1833~~1834	0	(0.0, 0.2)
		~~Headache[d]~~ Headache[e]						
-	-	Any	~~1860~~1867	~~733 (39.4)~~ 742 (39.7)	~~(37.2, 41.7)~~ (37.5, 42.0)	1833	259 (14.1)	(12.6, 15.8)

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	~~1860~~1867	~~464 (24.9)~~ 468 (25.1)	~~(23.0, 27.0)~~ (23.1, 27.1)	1833	189 (10.3)	(9.0, 11.8)
-	-	Moderate	~~1860~~1867	~~256 (13.8)~~ 261 (14.0)	~~(12.2, 15.4)~~ (12.4, 15.6)	1833	65 (3.5)	(2.7, 4.5)
-	-	Severe	~~1860~~1867	13 (0.7)	(0.4, 1.2)	1833	5 (0.3)	(0.1, 0.6)
-	-	Grade 4	~~1860~~1867	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
-	-	~~Chills~~[d] Chills[e]	-	-	-	-	-	-
-	-	Any	~~1860~~1864	~~435 (23.4)~~	~~(21.5, 25.4)~~	1833	57 (3.1)	(2.4, 4.0)
-	-	Mild	~~1860~~1864	~~229 (12.3)~~	~~(10.9, 13.9)~~	1833	45 (2.5)	(1.8, 3.3)
-	-	Moderate	~~1860~~1864	~~185 (9.9)~~	~~(8.6, 11.4)~~	1833	12 (0.7)	(0.3, 1.1)
-	-	Severe	~~1860~~1864	21 (1.1)	(0.7, 1.7)	1833	0	(0.0, 0.2)
-	-	Grade 4	~~1860~~1864	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
-	-	~~Vomiting~~[e] 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~~[f]Diarrhea[g]						
		Any	1860	~~152~~154 (8.~~2~~3)	(7.~~0~~1, 9.~~5~~6)	~~1833~~1834	~~102~~103 (5.6)	(4.6, 6.~~7~~8)
		Mild	1860	~~125~~126 (6.~~7~~8)	(5.~~6~~7, 8.0)	~~1833~~1834	~~76~~77 (4.~~1~~2)	(3.3, 5.2)

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	1860	~~25~~26 (1.~~3~~4)	(0.9, 2.0)	~~1833~~1834	22 (1.2)	(0.8, 1.8)
		Severe	1860	2 (0.1)	(0.0, 0.4)	~~1833~~1834	4 (0.2)	(0.1, 0.6)
		Grade 4	1860	0	(0.0, 0.2)	~~1833~~1834	0	(0.0, 0.2)
		New or worsened muscle ~~pain[d]~~pain[e]						
		Any	~~1860~~1863	~~537 (28.9~~540 (29.0)	(26.~~8~~9, 31.~~0~~1)	1833	99 (5.4)	(4.4, 6.5)
		Mild	~~1860~~1863	229 (12.3)	(10.~~9~~8, 13.9)	1833	65 (3.5)	(2.7, 4.5)
		Moderate	~~1860~~1863	~~288~~291 (15.~~5~~6)	(~~13.9~~14.0, 17.~~2~~3)	1833	33 (1.8)	(1.2, 2.5)
		Severe	~~1860~~1863	20 (1.1)	(0.7, 1.7)	1833	1 (0.1)	(0.0, 0.3)
		Grade 4	~~1860~~1863	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		New or worsened joint ~~pain[d]~~pain[e]						
		Any	~~1860~~1861	~~353~~355 (19.~~0~~1)	(17.~~2~~3, 20.~~8~~9)	1833	72 (3.9)	(3.1, 4.9)
		Mild	~~1860~~1861	~~183~~184 (9.~~8~~9)	(8.~~5~~6, 11.3)	1833	44 (2.4)	(1.7, 3.2)
		Moderate	~~1860~~1861	~~161~~162 (8.7)	(7.~~4~~5, 10.~~0~~1)	1833	27 (1.5)	(1.0, 2.1)
		Severe	~~1860~~1861	9 (0.5)	(0.2, 0.9)	1833	1 (0.1)	(0.0, 0.3)
		Grade 4	~~1860~~1861	0	(0.0, 0.2)	1833	0	(0.0, 0.2)
		Any systemic ~~event[g]~~event[h]	~~1860~~1868	~~1203 (64.7~~1214 (65.0)	(62.~~5, 66.9~~8, 67.2)	~~1833~~1835	~~516~~518 (28.2)	(26.~~1~~2, 30.3)
		Use of antipyretic or pain ~~medication[h]~~medication[i]	1860	688 (37.0)	(34.8, 39.2)	1833	170 (9.3)	(8.0, 10.7)

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])
	Any dose	Fever						
		~~≥38.0°C~~Any	2015	~~232~~238 (11.~~5~~8)	(10.~~2~~4, 13.~~0~~3)	1994	~~11~~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[d]~~ Fatigue[e]						
		Any	2015	~~1147 (56.9~~1148 (57.0)	(54.~~7~~8, 59.1)	1994	~~586~~587 (29.4)	(27.4, 31.~~4~~5)
		Mild	2015	485 (24.1)	(22.2, 26.0)	1994	~~341~~342 (17.~~1~~2)	(15.5, 18.~~8~~9)
		Moderate	2015	~~598~~599 (29.7)	(27.7, 31.~~7~~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[d]~~Headache[e]						
		Any	2015	~~925 (45.9~~931 (46.2)	(~~43.7~~44.0, 48.~~1~~4)	~~1994~~1995	~~492~~494 (24.~~7~~8)	(22.~~8~~9, 26.~~6~~7)
		Mild	2015	~~588~~589 (29.2)	(27.~~2~~3, 31.~~2~~3)	~~1994~~1995	~~345~~347 (17.~~3~~4)	(15.~~7~~8, 19.~~0~~1)
		Moderate	2015	~~322~~327 (16.~~0~~2)	(14.~~4~~6, 17.~~7~~9)	~~1994~~1995	139 (7.0)	(5.9, 8.2)
		Severe	2015	15 (0.7)	(0.4, 1.2)	~~1994~~1995	8 (0.4)	(0.2, 0.8)
		Grade 4	2015	0	(0.0, 0.2)	~~1994~~1995	0	(0.0, 0.2)
		~~Chills[d]~~Chills[e]						

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])
		Any	2015	~~499 (24.8~~505 (25.1)	(~~22.9, 26.7~~23.2, 27.0)	1994	110 (5.5)	(4.6, 6.6)
		Mild	2015	~~276~~281 (13.~~7~~9)	(12.~~2~~5, 15.~~3~~5)	1994	80 (4.0)	(3.2, 5.0)
		Moderate	2015	~~202~~203 (10.~~0~~1)	(8.~~7~~8, 11.~~4~~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~~[e]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~~[f]Diarrhea[g]						
		Any	2015	~~266~~268 (13.~~2~~3)	(11.8, 14.~~8~~9)	~~1994~~1995	~~199~~201 (10.~~0~~1)	(8.~~7~~8, 11.~~4~~5)
		Mild	2015	~~210~~211 (10.~~4~~5)	(9.~~1~~2, 11.~~8~~9)	~~1994~~1995	~~155~~157 (7.~~8~~9)	(6.~~6~~7, 9.~~0~~1)
		Moderate	2015	~~50~~51 (2.5)	(1.~~8~~9, 3.3)	~~1994~~1995	39 (2.0)	(1.4, 2.7)
		Severe	2015	6 (0.3)	(0.1, 0.6)	~~1994~~1995	5 (0.3)	(0.1, 0.6)
		Grade 4	2015	0	(0.0, 0.2)	~~1994~~1995	0	(0.0, 0.2)
		New or worsened muscle ~~pain~~[d]pain[e]						
		Any	2015	~~655~~657 (32.~~5~~6)	(30.~~5~~6, 34.~~6~~7)	1994	221 (11.1)	(9.7, 12.5)
		Mild	2015	296 (14.7)	(13.2, 16.3)	1994	138 (6.9)	(5.8, 8.1)

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	~~338~~340 (16.~~8~~9)	(15.~~2~~3, 18.~~5~~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[d]~~pain[e]						
		Any	2015	~~433~~435 (21.~~5~~6)	(19.~~7~~8, 23.~~3~~5)	1994	170 (8.5)	(7.3, 9.8)
		Mild	2015	~~227~~228 (11.3)	(~~9.9~~10.0, 12.~~7~~8)	1994	98 (4.9)	(4.0, 6.0)
		Moderate	2015	~~194~~195 (9.~~6~~7)	(8.4, 11.~~0~~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[g]~~event[h]	2015	~~1432~~1436 (71.~~1~~3)	(69.~~0~~2, 73.~~0~~2)	~~1994~~1995	~~919~~922 (46.~~1~~2)	(~~43.9~~44.0, 48.~~3~~4)
		Use of antipyretic or pain ~~medication[h]~~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.~~

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.

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])

~~e~~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.

~~f~~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.

~~g~~h. Any systemic event: any fever ~~≥38.0°C~~, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.

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

PFIZER CONFIDENTIAL SDTM Creation: ~~25MAR2021 (19:~~29APR2021 (22:11) Source Data: adfacevd Table Generation: ~~27MAR2021 (01:55~~29APR2021 (23:24)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_~~BLA~~sBLA_CBER_EDIARY/adce_s020_se_p3_saf

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~~≥38.0°C~~	54	2 (3.7~~1 (1.9~~)	(0.5, 12.7~~0, 9.9~~)	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]~~Fatigue[d]~~						
	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]~~Headache[d]~~						
	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]~~Chills[d]~~						
	Any	54	6 (11.1)	(4.2, 22.6)	56	5 (8.9)	(3.0, 19.6)

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])
	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)
	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] ~~Vomiting[e]~~						
	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] ~~Diarrhea[f]~~						
	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] ~~pain[d]~~						
	Any	55~~54~~	10 (18.2~~9 (16.7~~)	(~~7~~.9.1, 30.9~~, 29.3~~)	56	10 (17.9)	(8.9, 30.4)
	Mild	55~~54~~	7 (12.7~~13.0~~)	(5.3~~4~~, 24.5~~9~~)	56	7 (12.5)	(5.2, 24.1)
	Moderate	55~~54~~	~~2 (~~3 (5.5~~.7~~)	(1.1, 15.1~~0.5, 12.7~~)	56	3 (5.4)	(1.1, 14.9)
	Severe	55~~54~~	0	(0.0, 6.5~~6~~)	56	0	(0.0, 6.4)
	Grade 4	55~~54~~	0	(0.0, 6.5~~6~~)	56	0	(0.0, 6.4)
	New or worsened joint pain[e] ~~pain[d]~~						

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])
	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)
	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≥38.0°C	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)

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])
	Mild	6160	9 (14.8 (13.3)	(7.0, 26.25.9, 24.6)	62	8 (12.9)	(5.7, 23.9)
	Moderate	6160	8 (13.13)	(5.89, 24.26)	62	4 (6.5)	(1.8, 15.7)
	Severe	6160	2 (3.3)	(0.4, 11.35)	62	0	(0.0, 5.8)
	Grade 4	6160	0	(0.0, 5.96.0)	62	0	(0.0, 5.8)
	Chills[e]Chills[d]						
	Any	6160	16 (26.214 (23.3)	(15.8, 39.113.4, 36.0)	62	4 (6.5)	(1.8, 15.7)
	Mild	6160	6 (9.5 (8.3)	(3.7, 20.2.8, 18.4)	62	3 (4.8)	(1.0, 13.5)
	Moderate	6160	8 (13.13)	(5.89, 24.26)	62	1 (1.6)	(0.0, 8.7)
	Severe	6160	2 (3.31 (1.7)	(0.4, 11.30, 8.9)	62	0	(0.0, 5.8)
	Grade 4	6160	0	(0.0, 5.96.0)	62	0	(0.0, 5.8)
	Vomiting[f]Vomiting[e]						
	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	01 (1.7)	(0.0, 6.08.9)	62	1 (1.6)	(0.0, 8.7)
	Severe	60	1 (1.7)0	(0.0, 8.96.0)	62	0	(0.0, 5.8)
	Grade 4	60	0	(0.0, 6.0)	62	0	(0.0, 5.8)
	Diarrhea[g]Diarrhea[f]						
	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]pain[d]						

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])
	Any	6160	12 (1910 (16.7)	(10.6, 31.8.3, 28.5)	62	5 (8.1)	(2.7, 17.8)
	Mild	6160	7 (11.5 (8.3)	(2.8, 18.4.7, 22.2)	62	1 (1.6)	(0.0, 8.7)
	Moderate	6160	4 (6.65 (8.3)	(12.8, 15.918.4)	62	4 (6.5)	(1.8, 15.7)
	Severe	6160	1 (1.6)0	(0.0, 8.86.0)	62	0	(0.0, 5.8)
	Grade 4	6160	0	(0.0, 5.96.0)	62	0	(0.0, 5.8)
	New or worsened joint pain[e]pain[d]						
	Any	6160	11 (18.010 (16.7)	(9.4, 30.08.3, 28.5)	62	5 (8.1)	(2.7, 17.8)
	Mild	6160	5 (8.24 (6.7)	(1.8, 16.2.7, 18.1)	62	1 (1.6)	(0.0, 8.7)
	Moderate	6160	6 (9.810.0)	(3.78, 20.25)	62	4 (6.5)	(1.8, 15.7)
	Severe	6160	0	(0.0, 5.96.0)	62	0	(0.0, 5.8)
	Grade 4	6160	0	(0.0, 5.96.0)	62	0	(0.0, 5.8)
	Any systemic event[h]event[g]	6260	39 (62.936 (60.0)	(49.7, 74.846.5, 72.4)	6362	24 (3823 (37.1)	(26.1, 51125.2, 50.3)
	Use of antipyretic or pain medication[i]medication[h]	60	16 (26.7)	(16.1, 39.7)	62	7 (11.3)	(4.7, 21.9)
Any dose	Fever						
	Any≥38.0°C	7372	14 (19.29 (12.5)	(105.9, 30.122.4)	74	7 (9.5)	(3.9, 18.5)
	≥38.0°C to 38.4°C	7372	4 (5.56)	(1.5, 13.46)	74	5 (6.8)	(2.2, 15.1)
	>38.4°C to 38.9°C	7372	4 (5.56)	(1.5, 13.46)	74	0	(0.0, 4.9)
	>38.9°C to 40.0°C	7372	1 (1.4)	(0.0, 7.45)	74	2 (2.7)	(0.3, 9.4)
	>40.0°C	7372	0	(0.0, 4.95.0)	74	0	(0.0, 4.9)
	Unknown[d]	73	5 (6.8)	(2.3, 15.3)	74	0	(0.0, 4.9)
	Fatigue[e]Fatigue[d]						

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])
	Any	7472	36 (48.634 (47.2)	(36.9, 60.635.3, 59.3)	7574	21 (2820 (27.0)	(18.2, 3917.4, 38.6)
	Mild	7472	20 (2718 (25.0)	(17.4, 3815.5, 36.6)	7574	9 (12.08 (10.8)	(5.6, 21.64.8, 20.2)
	Moderate	7472	13 (17.618.1)	(9.710.0, 28.29)	7574	11 (14.79)	(7.6, 24.7, 25.0)
	Severe	7472	3 (4.12)	(0.89, 11.47)	7574	1 (1.34)	(0.0, 7.23)
	Grade 4	7472	0	(0.0, 4.95.0)	7574	0	(0.0, 4.89)
	Headache[e] Headache[d]						
	Any	7372	25 (34.224 (33.3)	(23.5, 46.322.7, 45.4)	74	23 (31.1)	(20.8, 42.9)
	Mild	7372	13 (17.812 (16.7)	(8.9.8, 28.5, 27.3)	74	13 (17.6)	(9.7, 28.2)
	Moderate	7372	10 (13.79)	(6.8, 23.89, 24.1)	74	9 (12.2)	(5.7, 21.8)
	Severe	7372	2 (2.78)	(0.3, 9.57)	74	1 (1.4)	(0.0, 7.3)
	Grade 4	7372	0	(0.0, 4.95.0)	74	0	(0.0, 4.9)
	Chills[e] Chills[d]						
	Any	7372	19 (26.017 (23.6)	(16.5, 37.614.4, 35.1)	74	9 (12.2)	(5.7, 21.8)
	Mild	7372	8 (11.07 (9.7)	(4.9, 20.50, 19.0)	74	7 (9.5)	(3.9, 18.5)
	Moderate	7372	9 (12.35)	(5.89, 22.14)	74	2 (2.7)	(0.3, 9.4)
	Severe	7372	2 (2.71 (1.4)	(0.3, 90, 7.5)	74	0	(0.0, 4.9)
	Grade 4	7372	0	(0.0, 4.95.0)	74	0	(0.0, 4.9)
	Vomiting[f] Vomiting[e]						
	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	01 (1.4)	(0.0, 7.5.0)	74	0	(0.0, 4.9)
	Severe	72	1 (1.4)0	(0.0, 7.5.0)	74	2 (2.7)	(0.3, 9.4)
	Grade 4	72	0	(0.0, 5.0)	74	0	(0.0, 4.9)

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])
	Diarrhea[g] ~~Diarrhea[f]~~						
	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)
	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] ~~pain[d]~~						
	Any	73~~72~~	19 (26.0~~17 (23.6~~)	(16.5, 37.6~~14.4, 35.1~~)	74	14 (18.9)	(10.7, 29.7)
	Mild	73~~72~~	13 (17.8~~11 (15.3~~)	(~~7.~~9.8, 28.5~~, 25.7~~)	74	8 (10.8)	(4.8, 20.2)
	Moderate	73~~72~~	5 (6.~~ (~~8.3~~)	(2.3, 15.~~1, 17~~.3)	74	6 (8.1)	(3.0, 16.8)
	Severe	73~~72~~	1 (1.4)~~0~~	(0.0, 7.4~~5.0~~)	74	0	(0.0, 4.9)
	Grade 4	73~~72~~	0	(0.0, 4.9~~5.0~~)	74	0	(0.0, 4.9)
	New or worsened joint pain[e] ~~pain[d]~~						
	Any	73~~72~~	14 (19.2~~13 (18.1~~)	(10.~~0, 28.~~9, 30.1)	74	11 (14.9)	(7.7, 25.0)
	Mild	73~~72~~	8 (11.0~~7 (9.7~~)	(4.9, 20.5~~0, 19.0~~)	74	5 (6.8)	(2.2, 15.1)
	Moderate	73~~72~~	6 (8.2~~3~~)	(3.1, 17.0~~3~~)	74	6 (8.1)	(3.0, 16.8)
	Severe	73~~72~~	0	(0.0, 4.9~~5.0~~)	74	0	(0.0, 4.9)
	Grade 4	73~~72~~	0	(0.0, 4.9~~5.0~~)	74	0	(0.0, 4.9)
	Any systemic event[h] ~~event[g]~~	74~~72~~	52 (70.3~~50 (69.4~~)	(58~~57~~.5, 80.3~~79.8~~)	75~~74~~	40 (53.3~~39 (52.7~~)	(41.4~~40.7~~, 64.9~~4~~)
	Use of antipyretic or pain medication[i] ~~medication[h]~~	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

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])

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.

~~d.~~ 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~~e~~. 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~~f~~. 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~~g~~. Any systemic event: any fever ~~≥38.0°C~~, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.

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

PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (~~25MAR2021 (19:~~22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:24~~27MAR2021 (01:55~~)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:

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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 ~~≥38.0°C~~	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] ~~Fatigue[d]~~						
		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] ~~Headache[d]~~						
		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] ~~Chills[d]~~						

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	49 (27.7)	(21.2, 34.9)	187	8 (4.7 (3.7)	(1.9, 8.35, 7.6)
		Mild	177	33 (18.6)	(13.2, 25.2)	187	54 (2.71)	(0.9, 6.1, 5.4)
		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]~~Vomiting[e]~~						
		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]~~Diarrhea[f]~~						
		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]~~pain[d]~~						
		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)

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	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]~~pain~~[d]						
		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]~~event~~[g]	177	115 (65.0)	(57.5, 72.0)	187	77 (41.2)	(34.0, 48.6)
		Use of antipyretic or pain medication[i]~~medication~~[h]	177	67 (37.9)	(30.7, 45.4)	187	28 (15.0)	(10.2, 20.9)
	2	Fever						
		Any~~≥38.0°C~~	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)

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])
		Fatigue[e] ~~Fatigue[d]~~						
		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] ~~Headache[d]~~						
		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] ~~Chills[d]~~						
		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] ~~Vomiting[e]~~						
		Any	153	2 (1.3)	(0.2, 4.6)	165	4 (2.4)	(0.7, 6.1)

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])
		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] ~~Diarrhea[f]~~						
		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)
		Grade 4	153	0	(0.0, 2.4)	165	0	(0.0, 2.2)
		New or worsened muscle pain[e] ~~pain[d]~~						
		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] ~~pain[d]~~						
		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)

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	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] ~~event[g]~~	153	87 (56.9)	(48.6, 64.8)	165	50 (30.3)	(23.4, 37.9)
		Use of antipyretic or pain medication[i] ~~medication[h]~~	153	48 (31.4)	(24.1, 39.4)	165	16 (9.7)	(5.6, 15.3)
	Any dose	Fever						
		Any ~~≥38.0°C~~	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)
		Unknown[d]	177	0	(0.0, 2.1)	187	0	(0.0, 2.0)
		Fatigue[e] ~~Fatigue[d]~~						
		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)

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])
		Headache[e] ~~Headache[d]~~						
		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] ~~Chills[d]~~						
		Any	177	58 (32.8)	(25.9, 40.2)	187	10 (5.3~~9 (4.8~~)	(2.6, ~~2, 8.~~9.6)
		Mild	177	34 (19.2)	(13.7, 25.8)	187	7~~6~~ (3.7~~2~~)	(1.5, 7.~~2, 6.9~~)
		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] ~~Vomiting[e]~~						
		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)
		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] ~~Diarrhea[f]~~						
		Any	177	18 (10.2)	(6.1, 15.6)	187	27 (14.4)	(9.7, 20.3)

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])
		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]~~pain[d]~~						
		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]~~pain[d]~~						
		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]~~event[g]~~	177	129 (72.9)	(65.7, 79.3)	187	96 (51.3)	(43.9, 58.7)
		Use of antipyretic or pain medication[i]~~medication[h]~~	177	77 (43.5)	(36.1, 51.1)	187	38 (20.3)	(14.8, 26.8)

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])
Negative	1	Fever						
		Any~~≥38.0°C~~	4701	123~~121~~ (2.6)	(2.2~~1~~, 3.1)	4690	30~~29~~ (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]~~Fatigue[d]~~						
		Any	4702~~4701~~	2013~~2011~~ (42.8)	(41.4, 44.2)	4690	1368 (29.2)	(27.9, 30.5)
		Mild	4702~~4701~~	1140~~1138~~ (24.2)	(23.0, 25.5)	4690	829 (17.7)	(16.6, 18.8)
		Moderate	4702~~4701~~	832 (17.7)	(16.6, 18.8)	4690	519 (11.1)	(10.2, 12.0)
		Severe	4702~~4701~~	41 (0.9)	(0.6, 1.2)	4690	20 (0.4)	(0.3, 0.7)
		Grade 4	4702~~4701~~	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Headache[e]~~Headache[d]~~						
		Any	4703~~4701~~	1682~~1680~~ (35.8~~7~~)	(34.4, 37.2~~1~~)	4692~~4690~~	1294~~1291~~ (27.6~~5~~)	(26.3, 28.9~~8~~)
		Mild	4703~~4701~~	1124~~1122~~ (23.9)	(22.7, 25.1)	4692~~4690~~	867~~865~~ (18.5~~4~~)	(17.4~~3~~, 19.6)
		Moderate	4703~~4701~~	527 (11.2)	(10.3, 12.1)	4692~~4690~~	403~~402~~ (8.6)	(7.8, 9.4)
		Severe	4703~~4701~~	31 (0.7)	(0.4, 0.9)	4692~~4690~~	24 (0.5)	(0.3, 0.8)
		Grade 4	4703~~4701~~	0	(0.0, 0.1)	4692~~4690~~	0	(0.0, 0.1)
		Chills[e]~~Chills[d]~~						

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	47024701	552549 (11.7)	(10.8, 12.76)	4690	260 (5.5)	(4.9, 6.2)
		Mild	47024701	402401 (8.5)	(7.87, 9.4)	4690	192 (4.1)	(3.5, 4.7)
		Moderate	47024701	138136 (2.9)	(2.54, 3.54)	4690	65 (1.4)	(1.1, 1.8)
		Severe	47024701	12 (0.3)	(0.1, 0.4)	4690	3 (0.1)	(0.0, 0.2)
		Grade 4	47024701	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		Vomiting[f]Vomiting[e]						
		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]Diarrhea[f]						
		Any	4701	462 (9.8)	(9.0, 10.7)	46914690	441439 (9.4)	(8.65, 10.32)
		Mild	4701	375 (8.0)	(7.2, 8.8)	46914690	364362 (7.87)	(7.0, 8.65)
		Moderate	4701	80 (1.7)	(1.4, 2.1)	46914690	75 (1.6)	(1.3, 2.0)
		Severe	4701	7 (0.1)	(0.1, 0.3)	46914690	2 (0.0)	(0.0, 0.2)
		Grade 4	4701	0	(0.0, 0.1)	46914690	0	(0.0, 0.1)
		New or worsened muscle pain[e]pain[d]						
		Any	47024701	878875 (18.76)	(17.65, 19.8)	4690	471 (10.0)	(9.2, 10.9)
		Mild	47024701	517515 (11.0)	(10.1, 11.9)	4690	327 (7.0)	(6.3, 7.7)

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	4702~~4701~~	348~~347~~ (7.4)	(6.7~~6~~, 8.2)	4690	139 (3.0)	(2.5, 3.5)
		Severe	4702~~4701~~	13 (0.3)	(0.1, 0.5)	4690	5 (0.1)	(0.0, 0.2)
		Grade 4	4702~~4701~~	0	(0.0, 0.1)	4690	0	(0.0, 0.1)
		New or worsened joint pain[e]~~pain[d]~~						
		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]~~event[g]~~	4703~~4701~~	2830~~2825~~ (60.2~~1~~)	(58.8~~7~~, 61.6~~5~~)	4692~~4690~~	2226~~2223~~ (47.4)	(46.0, 48.9~~8~~)
		Use of antipyretic or pain medication[i]~~medication[h]~~	4701	1109 (23.6)	(22.4, 24.8)	4690	592 (12.6)	(11.7, 13.6)
	2	Fever						
		Any~~≥38.0°C~~	4379~~4368~~	666 (15.2~~645 (14.8~~)	(14.2, 16.3~~13.7, 15.9~~)	4335~~4334~~	15~~13~~ (0.3)	(0.2, 0.6~~5~~)
		≥38.0°C to 38.4°C	4379~~4368~~	399 (9.1)	(8.3, 10.0)	4335~~4334~~	7 (0.2)	(0.1, 0.3)
		>38.4°C to 38.9°C	4379~~4368~~	199 (4.5~~6~~)	(3.9~~4.0~~, 5.2)	4335~~4334~~	3 (0.1)	(0.0, 0.2)
		>38.9°C to 40.0°C	4379~~4368~~	46 (1.1)	(0.8, 1.4)	4335~~4334~~	3 (0.1)	(0.0, 0.2)
		>40.0°C	4379~~4368~~	1 (0.0)	(0.0, 0.1)	4335~~4334~~	0	(0.0, 0.1)
		Unknown[d]	4379	21 (0.5)	(0.3, 0.7)	4335	2 (0.0)	(0.0, 0.2)

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])
		Fatigue[e] ~~Fatigue[d]~~						
		Any	4378~~4368~~	2545~~2532~~ (58.1~~0~~)	(56.7~~5~~, 59.6~~4~~)	4335~~4334~~	893~~889~~ (20.6~~5~~)	(19.4~~3~~, 21.8~~7~~)
		Mild	4378~~4368~~	930~~923~~ (21.2~~1~~)	(20.0~~19.9~~, 22.5~~4~~)	4335~~4334~~	493~~489~~ (11.4~~3~~)	(10.4, 12.4~~3~~)
		Moderate	4378~~4368~~	1415~~1411~~ (32.3)	(30.9, 33.7)	4335~~4334~~	385 (8.9)	(8.1, 9.8)
		Severe	4378~~4368~~	199~~197~~ (4.5)	(3.9, 5.2)	4335~~4334~~	15 (0.3)	(0.2, 0.6)
		Grade 4	4378~~4368~~	1 (0.0)	(0.0, 0.1)	4335~~4334~~	0	(0.0, 0.1)
		Headache[e] ~~Headache[d]~~						
		Any	4381~~4368~~	2135~~2118~~ (48.7~~5~~)	(47.2~~0~~, 50.2~~0~~)	4336~~4334~~	880~~875~~ (20.3~~2~~)	(19.1~~0~~, 21.5~~4~~)
		Mild	4381~~4368~~	1139 (26.0~~1130 (25.9~~)	(24.7~~6~~, 27.3~~2~~)	4336~~4334~~	579~~574~~ (13.4~~2~~)	(12.4~~2~~, 14.4~~3~~)
		Moderate	4381~~4368~~	896~~889~~ (20.5~~4~~)	(19.3~~2~~, 21.7~~6~~)	4336~~4334~~	281 (6.5)	(5.8, 7.3)
		Severe	4381~~4368~~	100~~99~~ (2.3)	(1.9~~8~~, 2.8)	4336~~4334~~	20 (0.5)	(0.3, 0.7)
		Grade 4	4381~~4368~~	0	(0.0, 0.1)	4336~~4334~~	0	(0.0, 0.1)
		Chills[e] ~~Chills[d]~~						
		Any	4378~~4368~~	1431~~1417~~ (32.7~~4~~)	(31.3, 34.1~~, 33.9~~)	4334	169~~168~~ (3.9)	(3.3, 4.5)
		Mild	4378~~4368~~	699 (16.0~~690 (15.8~~)	(14.7~~, 16.~~9, 17.1)	4334	133~~132~~ (3.1~~0~~)	(2.6, 3.6)
		Moderate	4378~~4368~~	642~~637~~ (14.7~~6~~)	(13.6~~5~~, 15.7)	4334	34 (0.8)	(0.5, 1.1)
		Severe	4378~~4368~~	90 (2.1)	(1.7, 2.5)	4334	2 (0.0)	(0.0, 0.2)
		Grade 4	4378~~4368~~	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Vomiting[f] ~~Vomiting[e]~~						
		Any	4368	69 (1.6)	(1.2, 2.0)	4334	31 (0.7)	(0.5, 1.0)

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])
		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] ~~Diarrhea[f]~~						
		Any	4368	412~~410~~ (9.4)	(8.6~~5~~, 10.3)	4336~~4334~~	291~~289~~ (6.7)	(6.0~~5.9~~, 7.5)
		Mild	4368	338~~337~~ (7.7)	(7.0~~6.9~~, 8.6~~5~~)	4336~~4334~~	235~~233~~ (5.4)	(4.8~~7~~, 6.1)
		Moderate	4368	66~~65~~ (1.5)	(1.2, 1.9)	4336~~4334~~	53 (1.2)	(0.9, 1.6)
		Severe	4368	8 (0.2)	(0.1, 0.4)	4336~~4334~~	3 (0.1)	(0.0, 0.2)
		Grade 4	4368	0	(0.0, 0.1)	4336~~4334~~	0	(0.0, 0.1)
		New or worsened muscle pain[e] ~~pain[d]~~						
		Any	4381~~4368~~	1565~~1548~~ (35.7~~4~~)	(34.3, 37.2~~0, 36.9~~)	4334	319 (7.4)	(6.6, 8.2)
		Mild	4381~~4368~~	663~~654~~ (15.1~~0~~)	(14.1~~13.9~~, 16.2~~1~~)	4334	206 (4.8)	(4.1, 5.4)
		Moderate	4381~~4368~~	825~~817~~ (18.8~~7~~)	(17.7, 20.0~~6, 19.9~~)	4334	109 (2.5)	(2.1, 3.0)
		Severe	4381~~4368~~	77 (1.8)	(1.4, 2.2)	4334	4 (0.1)	(0.0, 0.2)
		Grade 4	4381~~4368~~	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		New or worsened joint pain[e] ~~pain[d]~~						
		Any	4371~~4368~~	969~~962~~ (22.2~~0~~)	(20.9~~8~~, 23.4~~3~~)	4334	209 (4.8)	(4.2, 5.5)
		Mild	4371~~4368~~	464~~461~~ (10.6)	(9.7, 11.6~~5~~)	4334	118 (2.3)	(2.3, 3.3)

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	4371~~4368~~	469~~465~~ (10.7~~6~~)	(9.8~~7~~, 11.7~~6~~)	4334	86 (2.0)	(1.6, 2.4)
		Severe	4371~~4368~~	36 (0.8)	(0.6, 1.1)	4334	5 (0.1)	(0.0, 0.3)
		Grade 4	4371~~4368~~	0	(0.0, 0.1)	4334	0	(0.0, 0.1)
		Any systemic event[h]~~event[g]~~	4396~~4368~~	3171 (72.1~~3137 (71.8~~)	(70.8~~5~~, 73.5~~1~~)	4339~~4334~~	1493~~1485~~ (34.4~~3~~)	(33.0~~32.9~~, 35.8~~7~~)
		Use of antipyretic or pain medication[i]~~medication[h]~~	4368	1845 (42.2)	(40.8, 43.7)	4334	470 (10.8)	(9.9, 11.8)
	Any dose	Fever						
		Any~~≥38.0°C~~	4718	736~~714~~ (15.6~~1~~)	(14.6~~1~~, 16.7~~2~~)	4709~~4708~~	42~~39~~ (0.9~~8~~)	(0.6, 1.2~~1~~)
		≥38.0°C to 38.4°C	4718	451 (9.6)	(8.7, 10.4)	4709~~4708~~	24 (0.5)	(0.3, 0.8)
		>38.4°C to 38.9°C	4718	213 (4.5)	(3.9, 5.1)	4709~~4708~~	9 (0.2)	(0.1, 0.4)
		>38.9°C to 40.0°C	4718	49 (1.0)	(0.8, 1.4)	4709~~4708~~	6 (0.1)	(0.0, 0.3)
		>40.0°C	4718	1 (0.0)	(0.0, 0.1)	4709~~4708~~	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]~~Fatigue[d]~~						
		Any	4718	3074~~3069~~ (65.2~~0~~)	(63.8~~7~~, 66.5~~4~~)	4708	1702~~1701~~ (36.2~~1~~)	(34.8, 37.5)
		Mild	4718	1119~~1118~~ (23.7)	(22.5, 25.0~~24.9~~)	4708	931~~930~~ (19.8)	(18.6, 20.9)
		Moderate	4718	1721~~1719~~ (36.5~~4~~)	(35.1, 37.9~~8~~)	4708	740 (15.7)	(14.7, 16.8)
		Severe	4718	233~~231~~ (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)

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])
		Headache[e] ~~Headache[d]~~						
		Any	4718	2718~~2708~~ (57.6~~4~~)	(56.2, 59.0~~, 58.8~~)	4710~~4708~~	1656~~1650~~ (35.2~~0~~)	(33.8~~7~~, 36.5~~4~~)
		Mild	4718	1414 (30.0~~1410 (29.9~~)	(28.7~~6~~, 31.3~~2~~)	4710~~4708~~	1040~~1035~~ (22.1~~0~~)	(20.9~~8~~, 23.3~~2~~)
		Moderate	4718	1179 (25.0~~1174 (24.9~~)	(23.8~~7~~, 26.3~~1~~)	4710~~4708~~	573~~572~~ (12.2~~1~~)	(11.2, 13.1)
		Severe	4718	125~~124~~ (2.6)	(2.2, 3.1)	4710~~4708~~	43 (0.9)	(0.7, 1.2)
		Grade 4	4718	0	(0.0, 0.1)	4710~~4708~~	0	(0.0, 0.1)
		Chills[e] ~~Chills[d]~~						
		Any	4718	1651 (35.0~~1638 (34.7~~)	(33.6~~4~~, 36.4~~1~~)	4708	370~~369~~ (7.9~~8~~)	(7.1, 8.7~~6~~)
		Mild	4718	841~~832~~ (17.8~~6~~)	(16.7~~6~~, 18.9~~8~~)	4708	279~~278~~ (5.9)	(5.3~~2~~, 6.6)
		Moderate	4718	710~~706~~ (15.0)	(14.0, 16.1~~0~~)	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] ~~Vomiting[e]~~						
		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] ~~Diarrhea[f]~~						
		Any	4718	737~~735~~ (15.6)	(14.6, 16.7~~6~~)	4709~~4708~~	633~~629~~ (13.4)	(12.5~~4~~, 14.4)

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])
		Mild	4718	587~~586~~ (12.4)	(11.5, 13.4)	4709~~4708~~	507~~503~~ (10.8~~7~~)	(9.9~~8~~, 11.7~~6~~)
		Moderate	4718	135~~134~~ (2.9~~8~~)	(2.4, 3.4)	4709~~4708~~	121 (2.6)	(2.1, 3.1)
		Severe	4718	15 (0.3)	(0.2, 0.5)	4709~~4708~~	5 (0.1)	(0.0, 0.2)
		Grade 4	4718	0	(0.0, 0.1)	4709~~4708~~	0	(0.0, 0.1)
		New or worsened muscle pain[e]~~pain[d]~~						
		Any	4718	1913~~1901~~ (40.5~~3~~)	(39.1, 42.0~~38.9, 41.7~~)	4708	658 (14.0)	(13.0, 15.0)
		Mild	4718	806~~802~~ (17.1~~0~~)	(16.0~~15.9~~, 18.2~~1~~)	4708	423 (9.0)	(8.2, 9.8)
		Moderate	4718	1019~~1011~~ (21.6~~4~~)	(20.4~~3~~, 22.8~~6~~)	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]~~pain[d]~~						
		Any	4718	1186~~1179~~ (25.1~~0~~)	(23.9~~8~~, 26.4~~3~~)	4708	422 (9.0)	(8.2, 9.8)
		Mild	4718	563~~560~~ (11.9)	(11.0, 12.9~~8~~)	4708	246 (5.2)	(4.6, 5.9)
		Moderate	4718	581~~577~~ (12.3~~2~~)	(11.4~~3~~, 13.3~~2~~)	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)
		Grade 4	4718	0	(0.0, 0.1)	4708	0	(0.0, 0.1)
		Any systemic event[h]~~event[g]~~	4718	3734~~3725~~ (79.1~~0~~)	(78.0~~77.8~~, 80.3~~1~~)	4710~~4708~~	2613~~2609~~ (55.5~~4~~)	(54.0, 56.9~~8~~)
		Use of antipyretic or pain medication[i]~~medication[h]~~	4718	2209 (46.8)	(45.4, 48.3)	4708	881 (18.7)	(17.6, 19.9)

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])

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.
~~d.~~ 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~~e~~. 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~~f~~. 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~~g~~. Any systemic event: any fever ~~≥38.0°C~~, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
i~~h~~. Severity was not collected for use of antipyretic or pain medication.
PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (~~25MAR2021 (19:~~22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:24~~27MAR2021 (01:55~~)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_sBLA_CBER_EDIARY~~BLA~~/adce_s020_se_base_p3_saf

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] ~~Fever (≥38.0°C)~~		
		n[b] ~~n~~[a]	120~~119~~	25
		Mean (SD)	1.2 (0.87)	1.7 (1.52)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 7)
		Unknown[c] ~~Unknown~~[b]	0	1
		Fatigue		
		n[b] ~~n~~[a]	1433~~1431~~	960
		Mean (SD)	2.5 (2.51~~50~~)	2.9 (2.93~~89~~)
		Median	1.0	2.0
		Min, max	(1, 23)	(1, 23)
		Unknown[c] ~~Unknown~~[b]	6	5
		Headache		
		n[b] ~~n~~[a]	1264~~1262~~	976~~975~~
		Mean (SD)	2.4 (2.45)	2.6 (2.62)
		Median	1.0	1.0
		Min, max	(1, 25)	(1, 22)
		Unknown[c] ~~Unknown~~[b]	5	4
		Chills		
		n[b] ~~n~~[a]	481~~479~~	200~~199~~
		Mean (SD)	1.6 (1.35~~34~~)	2.1 (2.77)
		Median	1.0	1.0
		Min, max	(1, 9)	(1, 31)

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

Age Group	Dose	Systemic Event	Vaccine Group (as Administered) BNT162b2 (30 µg)	Placebo
		Unknown[c]~~Unknown~~[b]	1	2
		Vomiting		
		n[b]~~n~~[a]	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]~~n~~[a]	309	324~~323~~
		Mean (SD)	2.0 (2.97)	1.8 (1.91)
		Median	1.0	1.0
		Min, max	(1, 39)	(1, 23)
		Unknown[c]~~Unknown~~[b]	1	0
		New or worsened muscle pain		
		n[b]~~n~~[a]	667~~664~~	329
		Mean (SD)	1.7 (1.77~~63~~)	2.0 (2.56)
		Median	1.0	1.0
		Min, max	(1, 20~~17~~)	(1, 31)
		Unknown[c]~~Unknown~~[b]	1	1
		New or worsened joint pain		
		n[b]~~n~~[a]	342	168
		Mean (SD)	1.6 (1.77~~74~~)	2.2 (2.38)
		Median	1.0	1.0
		Min, max	(1, 24)	(1, 17)
		Unknown[c]~~Unknown~~[b]	3~~2~~	0

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**
		Use of antipyretic or pain medication		
		n[b]~~n~~[a]	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]~~Unknown~~[b]	1	4
	2	Fever[a]~~Fever (≥38.0°C)~~		
		n[b]~~n~~[a]	456~~440~~	13~~11~~
		Mean (SD)	1.2 (1.03~~ (0.51~~)	2.4~~1~~ (2.02~~08~~)
		Median	1.0	1.0
		Min, max	(1, 19~~8~~)	(1, 6)
		Unknown[c]~~Unknown~~[b]	0	1
		Fatigue		
		n[b]~~n~~[a]	1659~~1649~~	617~~614~~
		Mean (SD)	2.2 (2.14)	2.8 (3.04)
		Median	1.0	2.0
		Min, max	(1, 35)	(1, 38)
		Unknown[c]~~Unknown~~[b]	5	10
		Headache		
		n[b]~~n~~[a]	1456~~1448~~	657~~652~~
		Mean (SD)	2.2 (2.19~~01~~)	2.5~~4~~ (3.01~~00~~)
		Median	1.0	1.0
		Min, max	(1, 42~~25~~)	(1, 35)
		Unknown[c]~~Unknown~~[b]	5	10

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**
		Chills		
		n[b][a]	1024~~1015~~	115~~114~~
		Mean (SD)	1.3 (0.82~~81~~)	2.2 (1.98~~99~~)
		Median	1.0	1.0
		Min, max	(1, 11)	(1, 10)
		Unknown[c]~~Unknown[b]~~	3	2
		Vomiting		
		n[b][a]	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]~~Unknown[b]~~	1	1
		Diarrhea		
		n[b][a]	269	206~~205~~
		Mean (SD)	1.8 (2.31)	2.2~~1~~ (3.33~~32~~)
		Median	1.0	1.0
		Min, max	(1, 31)	(1, 33)
		Unknown[c]~~Unknown[b]~~	1	3
		New or worsened muscle pain		
		n[b][a]	1069~~1055~~	237
		Mean (SD)	1.5 (1.35~~34~~)	2.3 (2.71)
		Median	1.0	1.0
		Min, max	(1, 23)	(1, 27)
		Unknown[c]~~Unknown[b]~~	3	1

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**
		New or worsened joint pain		
		n[b] ~~n~~[a]	643~~638~~	147
		Mean (SD)	1.6 (1.77~~75~~)	2.2 (2.28)
		Median	1.0	1.0
		Min, max	(1, 28)	(1, 16)
		Unknown[c] ~~Unknown~~[b]	5	2
		Use of antipyretic or pain medication		
		n[b] ~~n~~[a]	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] ~~Unknown~~[b]	6	9
>55 Years	1	Fever[a] ~~Fever (≥38.0°C)~~		
		n[b] ~~n~~[a]	27~~26~~	9~~8~~
		Mean (SD)	1.2~~1~~ (0.48~~33~~)	1.9 (2.32~~0 (2.45~~)
		Median	1.0	1.0
		Min, max	(1, 3~~2~~)	(1, 8)
		Fatigue		
		n[b] ~~n~~[a]	677	447
		Mean (SD)	2.4 (2.74)	2.8 (3.43~~40~~)
		Median	1.0	1.0
		Min, max	(1, 34)	(1, 23)
		Unknown[c] ~~Unknown~~[b]	1	3
		Headache		

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] ~~n~~[a]	503	365~~363~~
		Mean (SD)	2.0 (1.86)	2.3 (2.65~~66~~)
		Median	1.0	1.0
		Min, max	(1, 17)	(1, 20)
		Unknown[c] ~~Unknown~~[b]	0	4
		Chills		
		n[b] ~~n~~[a]	131~~130~~	69
		Mean (SD)	1.6 (1.35)	2.1 (2.13)
		Median	1.0	1.0
		Min, max	(1, 11)	(1, 13)
		Unknown[c] ~~Unknown~~[b]	1	1
		Vomiting		
		n[b] ~~n~~[a]	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] ~~Unknown~~[b]	0	1
		Diarrhea		
		n[b] ~~n~~[a]	168	131~~130~~
		Mean (SD)	1.8 (1.58)	2.3 (3.34~~37~~)
		Median	1.0	1.0
		Min, max	(1, 8)	(1, 22)
		Unknown[c] ~~Unknown~~[b]	1	0~~1~~
		New or worsened muscle pain		

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] ~~n~~[a]	274	165
		Mean (SD)	1.5 (1.37)	1.98 (2.4644)
		Median	1.0	1.0
		Min, max	(1, 14)	(1, 18)
		Unknown[c] ~~Unknown~~[b]	1	0
		New or worsened joint pain		
		n[b] ~~n~~[a]	175	124
		Mean (SD)	1.9 (3.3226)	1.9 (2.33)
		Median	1.0	1.0
		Min, max	(1, 36)	(1, 17)
		Use of antipyretic or pain medication		
		n[b] ~~n~~[a]	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] ~~Unknown~~[b]	5	7
	2	Fever[a] ~~Fever (≥38.0°C)~~		
		n[b] ~~n~~[a]	224~~219~~	4
		Mean (SD)	1.1 (0.5435)	1.8 (1.50)
		Median	1.0	1.0
		Min, max	(1, 64)	(1, 4)
		Fatigue		
		n[b] ~~n~~[a]	952~~949~~	307~~306~~

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)	2.1 (1.88)	2.87 (4.9788)
		Median	1.0	1.0
		Min, max	(1, 20)	(1, 69)
		Unknown[c] ~~Unknown[b]~~	3	9
		Headache		
		n[b] ~~n~~[a]	742~~733~~	259
		Mean (SD)	1.8 (1.43)	2.4 (2.81)
		Median	1.0	1.0
		Min, max	(1, 12)	(1, 34)
		Unknown[c] ~~Unknown[b]~~	2	3
		Chills		
		n[b] ~~n~~[a]	440~~435~~	57
		Mean (SD)	1.2 (0.6362)	2.3 (2.72)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 16)
		Unknown[c] ~~Unknown[b]~~	1	2
		Vomiting		
		n[b] ~~n~~[a]	13	5
		Mean (SD)	1.2 (0.6038)	1.0 (0.00)
		Median	1.0	1.0
		Min, max	(1, 32)	(1, 1)
		Diarrhea		
		n[b] ~~n~~[a]	154~~152~~	103~~102~~
		Mean (SD)	1.8 (1.4543)	2.1 (2.83)

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**
		Median	1.0	1.0
		Min, max	(1, 9)	(1, 26)
		Unknown[c] ~~Unknown~~[b]	2	2
		New or worsened muscle pain		
		n[b] ~~n~~[a]	540~~537~~	99
		Mean (SD)	1.4 (0.97~~94~~)	1.6 (1.29)
		Median	1.0	1.0
		Min, max	(1, 7)	(1, 8)
		Unknown[c] ~~Unknown~~[b]	1	3
		New or worsened joint pain		
		n[b] ~~n~~[a]	355~~353~~	72
		Mean (SD)	1.~~65~~ (2.46~~02~~)	2.0 (1.71)
		Median	1.0	1.0
		Min, max	(1, 32)	(1, 8)
		Unknown[c] ~~Unknown~~[b]	2	1
		Use of antipyretic or pain medication		
		n[b] ~~n~~[a]	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] ~~Unknown~~[b]	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

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**

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~~b~~. Includes those events where the resolution date is partial or missing.

PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (22:06~~25MAR2021 (19:19~~) Source Data: adcevd Table Generation: 29APR2021 (23:22~~27MAR2021 (01:55~~)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:

./nda2 unblinded/C4591001 sBLA CBER EDIARY~~BLA~~/adce s040 se dur p3 saf

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] ~~Fever (≥38.0°C)~~		
	n[b] ~~n~~[a]	21	4
	Mean (SD)	1.5 (0.71 ~~(NE)~~)	1.8 (0.96)
	Median	1.5	1.5
	Min, max	(1, 21)	(1, 3)
	Fatigue		
	n[b] ~~n~~[a]	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] ~~n~~[a]	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] ~~Unknown~~[b]	0	1
	Chills		
	n[b] ~~n~~[a]	6	5
	Mean (SD)	2.6 (2.61 ~~(2.68~~)	1.8 (0.50)
	Median	1.0	2.0
	Min, max	(1, 7)	(1, 2)
	Unknown[c] ~~Unknown~~[b]	1	1

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

Dose	Systemic Event	Vaccine Group (as Administered) BNT162b2 (30 µg)	Vaccine Group (as Administered) Placebo
	Vomiting		
	n[b] ~~n[a]~~	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] ~~n[a]~~	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] ~~n[a]~~	10~~9~~	10
	Mean (SD)	1.6~~3~~ (0.97~~50~~)	2.0 (1.94~~8 (1.93~~)
	Median	1.0	1.0
	Min, max	(1, ~~4~~2)	(1, 7)
	New or worsened joint pain		
	n[b] ~~n[a]~~	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] ~~n[a]~~	7	8
	Mean (SD)	2.4 (2.15)	2.3 (1.91)
	Median	1.0	1.0

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**
	Min, max	(1, 6)	(1, 6)
2	Fever[a] ~~Fever (≥38.0°C)~~		
	n[b] ~~n~~[a]	13~~9~~	5
	Mean (SD)	2.0 (1.22~~4 (0.88~~)	1.8 (1.30)
	Median	2~~1~~.0	1.0
	Min, max	(1, 5~~3~~)	(1, 4)
	Fatigue		
	n[b] ~~n~~[a]	26~~24~~	13~~12~~
	Mean (SD)	3.~~3 (~~2 (2.54~~.63~~)	2.~~89~~ (1.91~~92~~)
	Median	2.0	2.0
	Min, max	(1, 10)	(1, 6)
	Unknown[c] ~~Unknown~~[b]	0	1
	Headache		
	n[b] ~~n~~[a]	19~~18~~	12
	Mean (SD)	2.2 (1.40 ~~(1.45~~)	2.3 (1.56)
	Median	2.0~~1.5~~	2.0
	Min, max	(1, 5)	(1, 5)
	Unknown[c] ~~Unknown~~[b]	0	1
	Chills		
	n[b] ~~n~~[a]	16~~14~~	4
	Mean (SD)	1.7 (1.08~~2 (0.43~~)	1.3 (0.50)
	Median	1.0	1.0
	Min, max	(1, 5~~2~~)	(1, 2)

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**
	Vomiting		
	n[b] ~~n~~[a]	2	2
	Mean (SD)	2~~1~~.0 (1.41~~0.00~~)	5.5 (2.12)
	Median	2~~1~~.0	5.5
	Min, max	(1, 3~~1~~)	(4, 7)
	Diarrhea		
	n[b] ~~n~~[a]	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] ~~n~~[a]	12~~10~~	5
	Mean (SD)	2.7 (1.56~~9 (1.60~~)	2.2 (1.64)
	Median	2.5~~1.0~~	2.0
	Min, max	(1, 6)	(1, 5)
	New or worsened joint pain		
	n[b] ~~n~~[a]	11~~10~~	5
	Mean (SD)	1.5 (0.93~~97~~)	1.2 (0.45)
	Median	1.0	1.0
	Min, max	(1, 4)	(1, 2)
	Use of antipyretic or pain medication		
	n[b] ~~n~~[a]	16	7
	Mean (SD)	2.0 (2.00)	1.6 (1.51)
	Median	1.0	1.0

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**
	Min, max	(1, 6)	(1, 5)

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~~b~~. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 29APR2021 (22:06~~25MAR2021 (19:19~~) Source Data: adcevd Table Generation: 29APR2021 (23:22~~27MAR2021 (01:55~~)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2_unblinded/C4591001_sBLA_CBER_EDIARY~~BLA~~/adce_s040_se_dur_hiv_p3_saf

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]~~Fever (≥38.0°C)~~		
		n[b]~~n~~[a]	120~~119~~	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]~~n~~[a]	1433~~1431~~	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]~~n~~[a]	1264~~1262~~	976~~975~~
		Mean (SD)	2.4 (1.52~~53~~)	2.6 (1.71)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Chills		
		n[b]~~n~~[a]	481~~479~~	200~~199~~
		Mean (SD)	2.2 (1.23)	2.9 (1.78)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Vomiting		
		n[b]~~n~~[a]	34	36
		Mean (SD)	3.8 (1.85)	3.6 (2.03)

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] ~~n~~[a]	309	324~~323~~
		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] ~~n~~[a]	667~~664~~	329
		Mean (SD)	2.3 (1.21~~20~~)	3.1 (1.78)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		New or worsened joint pain		
		n[b] ~~n~~[a]	342	168
		Mean (SD)	2.6 (1.42~~43~~)	3.4 (1.61)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Any systemic event[c] ~~event~~[b]		
		n[b] ~~n~~[a]	1983~~1979~~	1560~~1559~~
		Mean (SD)	2.0 (1.21~~22~~)	2.3 (1.59)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Use of antipyretic or pain medication		

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] ~~n~~[a]	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] ~~Fever (≥38.0°C)~~		
		n[b] ~~n~~[a]	456~~440~~	13~~11~~
		Mean (SD)	2.0 (0.55~~53~~)	3.5~~6~~ (2.11~~25~~)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Fatigue		
		n[b] ~~n~~[a]	1659~~1649~~	617~~614~~
		Mean (SD)	1.9 (0.76)	2.4 (1.61~~60~~)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[b] ~~n~~[a]	1456~~1448~~	657~~652~~
		Mean (SD)	2.1 (1.01~~02~~)	2.8 (1.75)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Chills		
		n[b] ~~n~~[a]	1024~~1015~~	115~~114~~
		Mean (SD)	1.9 (0.54)	2.7 (1.64~~63~~)
		Median	2.0	2.0
		Min, max	(1, 6)	(1, 7)

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] ~~n~~[a]	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] ~~n~~[a]	269	206~~205~~
		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] ~~n~~[a]	1069~~1055~~	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] ~~n~~[a]	643~~638~~	147
		Mean (SD)	2.1 (0.80~~81~~)	3.3 (1.82)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)
		Any systemic event[c] ~~event~~[b]		
		n[b] ~~n~~[a]	2057~~2034~~	1032~~1026~~
		Mean (SD)	1.8 (0.85)	2.4 (1.62)
		Median	2.0	2.0

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] ~~n~~[a]	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] ~~Fever (≥38.0°C)~~		
		n[b] ~~n~~[a]	2726	98
		Mean (SD)	2.43 (1.2123)	3.9 (4.1.69 (1.64)
		Median	2.0	4.0
		Min, max	(1, 6)	(2, 7)
		Fatigue		
		n[b] ~~n~~[a]	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] ~~n~~[a]	503	365363
		Mean (SD)	2.5 (1.5152)	2.8 (1.75)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Chills		
		n[b] ~~n~~[a]	131130	69

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] ~~n~~[a]	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] ~~n~~[a]	168	131~~130~~
		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] ~~n~~[a]	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] ~~n~~[a]	175	124
		Mean (SD)	2.9 (1.62)	3.7 (1.78)
		Median	2.0	3.0
		Min, max	(1, 7)	(1, 7)

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

Age Group	Dose	Systemic Event	Vaccine Group (as Administered) BNT162b2 (30 µg)	Placebo
		Any systemic event[c]~~event[b]~~		
		n[b]~~n~~[a]	985~~984~~	751~~749~~
		Mean (SD)	2.2 (1.36~~37~~)	2.6 (1.64~~65~~)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Use of antipyretic or pain medication		
		n[b]~~n~~[a]	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]~~Fever (≥38.0°C)~~		
		n[b]~~n~~[a]	224~~219~~	4
		Mean (SD)	2.0 (0.35~~34~~)	4.3 (2.50)
		Median	2.0	4.5
		Min, max	(1, 6)	(1, 7)
		Fatigue		
		n[b]~~n~~[a]	952~~949~~	307~~306~~
		Mean (SD)	2.0 (0.95)	2.8 (1.78)
		Median	2.0	2.0
		Min, max	(1, 7)	(1, 7)
		Headache		
		n[b]~~n~~[a]	742~~733~~	259
		Mean (SD)	2.2 (1.12)	2.9 (1.87)
		Median	2.0	2.0

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] ~~n~~[a]	440~~435~~	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] ~~n~~[a]	13	5
		Mean (SD)	3.2 (2.05~~3 (1.97~~)	4.2 (1.79)
		Median	2.0	4.0
		Min, max	(1~~2~~, 7)	(2, 7)
		Diarrhea		
		n[b] ~~n~~[a]	154~~152~~	103~~102~~
		Mean (SD)	3.4 (1.72~~70~~)	3.5 (1.53~~52~~)
		Median	3.0	3.0
		Min, max	(1, 7)	(1, 7)
		New or worsened muscle pain		
		n[b] ~~n~~[a]	540~~537~~	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] ~~n~~[a]	355~~353~~	72

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

Age Group	Dose	Systemic Event	Vaccine Group (as Administered) 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]~~event[b]~~		
		n[b]~~n~~[a]	1214~~1203~~	518~~516~~
		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]~~n~~[a]	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~~b~~. Any systemic event: any fever ~~≥38.0°C~~, 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 (~~25MAR2021 (19:~~22:11) Source Data: adfacevd Table Generation: 29APR2021 (23:22~~27MAR2021 (01:55~~)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 sBLA CBER EDIARY~~BLA~~/adce s060 se onset p3 saf

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]~~Fever (≥38.0°C)~~		
	n[b]~~n~~[a]	2~~1~~	4
	Mean (SD)	2.0 (0.00~~NE~~)	2.5 (2.38)
	Median	2.0	1.5
	Min, max	(2, 2)	(1, 6)
	Fatigue		
	n[b]~~n~~[a]	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]~~n~~[a]	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]~~n~~[a]	6	5
	Mean (SD)	~~2.2 (~~1.8 (0.75~~17~~)	2.2 (2.68)
	Median	2.0	1.0
	Min, max	(1, 3~~4~~)	(1, 7)
	Vomiting		
	n[b]~~n~~[a]	1	3
	Mean (SD)	3.0 (NE)	2.0 (1.00)

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] ~~n[a]~~	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] ~~n[a]~~	10~~9~~	10
	Mean (SD)	3.3 (1.95~~2 (2.05~~)	2.2~~3~~ (1.40~~34~~)
	Median	2.5~~0~~	2.0
	Min, max	(1, 7)	(1, 5)
	New or worsened joint pain		
	n[b] ~~n[a]~~	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] ~~event[b]~~		
	n[b] ~~n[a]~~	33~~32~~	32
	Mean (SD)	2.0 (1.38~~40~~)	2.6 (1.76)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 7)
	Use of antipyretic or pain medication		

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] ~~n~~[a]	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] ~~Fever (≥38.0°C)~~		
	n[b] ~~n~~[a]	139	5
	Mean (SD)	2.26 (1.5974)	3.8 (2.39)
	Median	2.0	4.0
	Min, max	(1, 7)	(1, 7)
	Fatigue		
	n[b] ~~n~~[a]	26~~24~~	13~~12~~
	Mean (SD)	2.2~~3~~ (1.39~~40~~)	2.2~~3~~ (1.36~~37~~)
	Median	2.0	2.0
	Min, max	(1, 7)	(1, 6)
	Headache		
	n[b] ~~n~~[a]	19~~18~~	12
	Mean (SD)	2.5~~6~~ (1.61~~69~~)	3.9 (2.31)
	Median	2.0	4.0
	Min, max	(1, 7)	(1, 7)
	Chills		
	n[b] ~~n~~[a]	16~~14~~	4
	Mean (SD)	2.6~~9~~ (1.63~~61~~)	4.3 (2.63)
	Median	2.0	4.0
	Min, max	(1~~2~~, 7)	(2, 7)

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

Dose	Systemic Event	Vaccine Group (as Administered) BNT162b2 (30 µg)	Vaccine Group (as Administered) Placebo
	Vomiting		
	n[b] ~~n[a]~~	2	2
	Mean (SD)	1.5 ~~(~~0 (0.00~~.71~~)	2.0 (1.41)
	Median	1.0~~5~~	2.0
	Min, max	(1, 1~~2~~)	(1, 3)
	Diarrhea		
	n[b] ~~n[a]~~	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] ~~n[a]~~	12~~10~~	5
	Mean (SD)	1.~~89~~ (0.62~~57~~)	3.8 (2.49)
	Median	2.0	2.0
	Min, max	(1, 3)	(2, 7)
	New or worsened joint pain		
	n[b] ~~n[a]~~	11~~10~~	5
	Mean (SD)	3.0~~1~~ (2.14~~23~~)	4.6 (2.07)
	Median	2.0	5.0
	Min, max	(1, 7)	(2, 7)
	Any systemic event[c] ~~event[b]~~		
	n[b] ~~n[a]~~	39~~36~~	24~~23~~
	Mean (SD)	2.~~45~~ (1.60~~63~~)	2.~~2~~ (1 (1.36~~.37~~)
	Median	2.0	2.0

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] ~~n~~[a]	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~~b~~. Any systemic event: any fever ~~≥38.0°C~~, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.
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