Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 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	4907	262 (5.3)	(4.7, 6.0)	4897	48 (1.0)	(0.7, 1.3)
	Mild	4907	184 (3.7)	(3.2, 4.3)	4897	32 (0.7)	(0.4, 0.9)
	Moderate	4907	66 (1.3)	(1.0, 1.7)	4897	11 (0.2)	(0.1, 0.4)
	Severe	4907	12 (0.2)	(0.1, 0.4)	4897	5 (0.1)	(0.0, 0.2)
	Grade 4	4907	0	(0.0, 0.1)	4897	0	(0.0, 0.1)
	Swelling[d]						
	Any	4907	325 (6.6)	(5.9, 7.4)	4897	39 (0.8)	(0.6, 1.1)
	Mild	4907	211 (4.3)	(3.7, 4.9)	4897	17 (0.3)	(0.2, 0.6)
	Moderate	4907	106 (2.2)	(1.8, 2.6)	4897	20 (0.4)	(0.2, 0.6)
	Severe	4907	8 (0.2)	(0.1, 0.3)	4897	2 (0.0)	(0.0, 0.1)
	Grade 4	4907	0	(0.0, 0.1)	4897	0	(0.0, 0.1)
	Pain at the injection site[e]						
	Any	4907	3834 (78.1)	(77.0, 79.3)	4897	599 (12.2)	(11.3, 13.2)
	Mild	4907	2572 (52.4)	(51.0, 53.8)	4897	568 (11.6)	(10.7, 12.5)
	Moderate	4907	1219 (24.8)	(23.6, 26.1)	4897	28 (0.6)	(0.4, 0.8)
	Severe	4907	43 (0.9)	(0.6, 1.2)	4897	3 (0.1)	(0.0, 0.2)
	Grade 4	4907	0	(0.0, 0.1)	4897	0	(0.0, 0.1)
	Any local reaction[f]	4907	3877 (79.0)	(77.8, 80.1)	4897	639 (13.0)	(12.1, 14.0)
2	Redness[d]						
	Any	4542	284 (6.3)	(5.6, 7.0)	4517	32 (0.7)	(0.5, 1.0)
	Mild	4542	155 (3.4)	(2.9, 4.0)	4517	22 (0.5)	(0.3, 0.7)

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

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	**Local Reaction**	**N[a]**	**n[b] (%)**	**(95% CI[c])**	**N[a]**	**n[b] (%)**	**(95% CI[c])**
	Moderate	4542	108 (2.4)	(2.0, 2.9)	4517	9 (0.2)	(0.1, 0.4)
	Severe	4542	21 (0.5)	(0.3, 0.7)	4517	1 (0.0)	(0.0, 0.1)
	Grade 4	4542	0	(0.0, 0.1)	4517	0	(0.0, 0.1)
	Swelling[d]						
	Any	4542	328 (7.2)	(6.5, 8.0)	4517	18 (0.4)	(0.2, 0.6)
	Mild	4542	190 (4.2)	(3.6, 4.8)	4517	8 (0.2)	(0.1, 0.3)
	Moderate	4542	127 (2.8)	(2.3, 3.3)	4517	9 (0.2)	(0.1, 0.4)
	Severe	4542	11 (0.2)	(0.1, 0.4)	4517	1 (0.0)	(0.0, 0.1)
	Grade 4	4542	0	(0.0, 0.1)	4517	0	(0.0, 0.1)
	Pain at the injection site[e]						
	Any	4542	3331 (73.3)	(72.0, 74.6)	4517	455 (10.1)	(9.2, 11.0)
	Mild	4542	2147 (47.3)	(45.8, 48.7)	4517	422 (9.3)	(8.5, 10.2)
	Moderate	4542	1135 (25.0)	(23.7, 26.3)	4517	33 (0.7)	(0.5, 1.0)
	Severe	4542	49 (1.1)	(0.8, 1.4)	4517	0	(0.0, 0.1)
	Grade 4	4542	0	(0.0, 0.1)	4517	0	(0.0, 0.1)
	Any local reaction[f]	4542	3351 (73.8)	(72.5, 75.1)	4517	483 (10.7)	(9.8, 11.6)
Any dose	Redness[d]						
	Any	4924	486 (9.9)	(9.1, 10.7)	4915	72 (1.5)	(1.1, 1.8)
	Mild	4924	300 (6.1)	(5.4, 6.8)	4915	47 (1.0)	(0.7, 1.3)
	Moderate	4924	153 (3.1)	(2.6, 3.6)	4915	20 (0.4)	(0.2, 0.6)
	Severe	4924	33 (0.7)	(0.5, 0.9)	4915	5 (0.1)	(0.0, 0.2)
	Grade 4	4924	0	(0.0, 0.1)	4915	0	(0.0, 0.1)

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 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	4924	546 (11.1)	(10.2, 12.0)	4915	51 (1.0)	(0.8, 1.4)
	Mild	4924	329 (6.7)	(6.0, 7.4)	4915	21 (0.4)	(0.3, 0.7)
	Moderate	4924	198 (4.0)	(3.5, 4.6)	4915	27 (0.5)	(0.4, 0.8)
	Severe	4924	19 (0.4)	(0.2, 0.6)	4915	3 (0.1)	(0.0, 0.2)
	Grade 4	4924	0	(0.0, 0.1)	4915	0	(0.0, 0.1)
	Pain at the injection site[e]						
	Any	4924	4153 (84.3)	(83.3, 85.3)	4915	849 (17.3)	(16.2, 18.4)
	Mild	4924	2356 (47.8)	(46.4, 49.3)	4915	789 (16.1)	(15.0, 17.1)
	Moderate	4924	1709 (34.7)	(33.4, 36.1)	4915	57 (1.2)	(0.9, 1.5)
	Severe	4924	88 (1.8)	(1.4, 2.2)	4915	3 (0.1)	(0.0, 0.2)
	Grade 4	4924	0	(0.0, 0.1)	4915	0	(0.0, 0.1)
	Any local reaction[f]	4924	4187 (85.0)	(84.0, 86.0)	4915	903 (18.4)	(17.3, 19.5)

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.
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Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 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						
	≥38.0°C	4907	145 (3.0)	(2.5, 3.5)	4897	33 (0.7)	(0.5, 0.9)
	≥38.0°C to 38.4°C	4907	109 (2.2)	(1.8, 2.7)	4897	19 (0.4)	(0.2, 0.6)
	>38.4°C to 38.9°C	4907	27 (0.6)	(0.4, 0.8)	4897	8 (0.2)	(0.1, 0.3)
	>38.9°C to 40.0°C	4907	9 (0.2)	(0.1, 0.3)	4897	6 (0.1)	(0.0, 0.3)
	>40.0°C	4907	0	(0.0, 0.1)	4897	0	(0.0, 0.1)
	Fatigue[d]						
	Any	4907	2108 (43.0)	(41.6, 44.4)	4897	1407 (28.7)	(27.5, 30.0)
	Mild	4907	1175 (23.9)	(22.8, 25.2)	4897	851 (17.4)	(16.3, 18.5)
	Moderate	4907	889 (18.1)	(17.0, 19.2)	4897	535 (10.9)	(10.1, 11.8)
	Severe	4907	44 (0.9)	(0.7, 1.2)	4897	21 (0.4)	(0.3, 0.7)
	Grade 4	4907	0	(0.0, 0.1)	4897	0	(0.0, 0.1)
	Headache[d]						
	Any	4907	1765 (36.0)	(34.6, 37.3)	4897	1338 (27.3)	(26.1, 28.6)
	Mild	4907	1166 (23.8)	(22.6, 25.0)	4897	900 (18.4)	(17.3, 19.5)
	Moderate	4907	564 (11.5)	(10.6, 12.4)	4897	411 (8.4)	(7.6, 9.2)
	Severe	4907	35 (0.7)	(0.5, 1.0)	4897	27 (0.6)	(0.4, 0.8)
	Grade 4	4907	0	(0.0, 0.1)	4897	0	(0.0, 0.1)
	Chills[d]						
	Any	4907	609 (12.4)	(11.5, 13.4)	4897	268 (5.5)	(4.9, 6.1)
	Mild	4907	440 (9.0)	(8.2, 9.8)	4897	197 (4.0)	(3.5, 4.6)
	Moderate	4907	154 (3.1)	(2.7, 3.7)	4897	68 (1.4)	(1.1, 1.8)

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

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	4907	15 (0.3)	(0.2, 0.5)	4897	3 (0.1)	(0.0, 0.2)
	Grade 4	4907	0	(0.0, 0.1)	4897	0	(0.0, 0.1)
	Vomiting[e]						
	Any	4907	44 (0.9)	(0.7, 1.2)	4897	45 (0.9)	(0.7, 1.2)
	Mild	4907	38 (0.8)	(0.5, 1.1)	4897	39 (0.8)	(0.6, 1.1)
	Moderate	4907	6 (0.1)	(0.0, 0.3)	4897	5 (0.1)	(0.0, 0.2)
	Severe	4907	0	(0.0, 0.1)	4897	1 (0.0)	(0.0, 0.1)
	Grade 4	4907	0	(0.0, 0.1)	4897	0	(0.0, 0.1)
	Diarrhea[f]						
	Any	4907	477 (9.7)	(8.9, 10.6)	4897	453 (9.3)	(8.5, 10.1)
	Mild	4907	388 (7.9)	(7.2, 8.7)	4897	373 (7.6)	(6.9, 8.4)
	Moderate	4907	82 (1.7)	(1.3, 2.1)	4897	78 (1.6)	(1.3, 2.0)
	Severe	4907	7 (0.1)	(0.1, 0.3)	4897	2 (0.0)	(0.0, 0.1)
	Grade 4	4907	0	(0.0, 0.1)	4897	0	(0.0, 0.1)
	New or worsened muscle pain[d]						
	Any	4907	938 (19.1)	(18.0, 20.2)	4897	494 (10.1)	(9.3, 11.0)
	Mild	4907	536 (10.9)	(10.1, 11.8)	4897	342 (7.0)	(6.3, 7.7)
	Moderate	4907	386 (7.9)	(7.1, 8.7)	4897	147 (3.0)	(2.5, 3.5)
	Severe	4907	16 (0.3)	(0.2, 0.5)	4897	5 (0.1)	(0.0, 0.2)
	Grade 4	4907	0	(0.0, 0.1)	4897	0	(0.0, 0.1)
	New or worsened joint pain[d]						
	Any	4907	517 (10.5)	(9.7, 11.4)	4897	292 (6.0)	(5.3, 6.7)
	Mild	4907	319 (6.5)	(5.8, 7.2)	4897	190 (3.9)	(3.4, 4.5)

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

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	**Systemic Event**	**N[a]**	**n[b] (%)**	**(95% CI[c])**	**N[a]**	**n[b] (%)**	**(95% CI[c])**
	Moderate	4907	190 (3.9)	(3.3, 4.5)	4897	100 (2.0)	(1.7, 2.5)
	Severe	4907	8 (0.2)	(0.1, 0.3)	4897	2 (0.0)	(0.0, 0.1)
	Grade 4	4907	0	(0.0, 0.1)	4897	0	(0.0, 0.1)
	Any systemic event[g]	4907	2963 (60.4)	(59.0, 61.8)	4897	2308 (47.1)	(45.7, 48.5)
	Use of antipyretic or pain medication[h]	4907	1187 (24.2)	(23.0, 25.4)	4897	622 (12.7)	(11.8, 13.7)
2	Fever						
	≥38.0°C	4542	659 (14.5)	(13.5, 15.6)	4517	15 (0.3)	(0.2, 0.5)
	≥38.0°C to 38.4°C	4542	412 (9.1)	(8.3, 9.9)	4517	7 (0.2)	(0.1, 0.3)
	>38.4°C to 38.9°C	4542	200 (4.4)	(3.8, 5.0)	4517	5 (0.1)	(0.0, 0.3)
	>38.9°C to 40.0°C	4542	46 (1.0)	(0.7, 1.3)	4517	3 (0.1)	(0.0, 0.2)
	>40.0°C	4542	1 (0.0)	(0.0, 0.1)	4517	0	(0.0, 0.1)
	Fatigue[d]						
	Any	4542	2598 (57.2)	(55.7, 58.6)	4517	920 (20.4)	(19.2, 21.6)
	Mild	4542	949 (20.9)	(19.7, 22.1)	4517	500 (11.1)	(10.2, 12.0)
	Moderate	4542	1446 (31.8)	(30.5, 33.2)	4517	404 (8.9)	(8.1, 9.8)
	Severe	4542	202 (4.4)	(3.9, 5.1)	4517	16 (0.4)	(0.2, 0.6)
	Grade 4	4542	1 (0.0)	(0.0, 0.1)	4517	0	(0.0, 0.1)
	Headache[d]						
	Any	4542	2181 (48.0)	(46.6, 49.5)	4517	911 (20.2)	(19.0, 21.4)
	Mild	4542	1163 (25.6)	(24.3, 26.9)	4517	593 (13.1)	(12.2, 14.1)
	Moderate	4542	914 (20.1)	(19.0, 21.3)	4517	295 (6.5)	(5.8, 7.3)
	Severe	4542	104 (2.3)	(1.9, 2.8)	4517	23 (0.5)	(0.3, 0.8)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 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])
	Grade 4	4542	0	(0.0, 0.1)	4517	0	(0.0, 0.1)
	Chills[d]						
	Any	4542	1450 (31.9)	(30.6, 33.3)	4517	171 (3.8)	(3.2, 4.4)
	Mild	4542	706 (15.5)	(14.5, 16.6)	4517	134 (3.0)	(2.5, 3.5)
	Moderate	4542	654 (14.4)	(13.4, 15.5)	4517	35 (0.8)	(0.5, 1.1)
	Severe	4542	90 (2.0)	(1.6, 2.4)	4517	2 (0.0)	(0.0, 0.2)
	Grade 4	4542	0	(0.0, 0.1)	4517	0	(0.0, 0.1)
	Vomiting[e]						
	Any	4542	71 (1.6)	(1.2, 2.0)	4517	35 (0.8)	(0.5, 1.1)
	Mild	4542	52 (1.1)	(0.9, 1.5)	4517	25 (0.6)	(0.4, 0.8)
	Moderate	4542	13 (0.3)	(0.2, 0.5)	4517	10 (0.2)	(0.1, 0.4)
	Severe	4542	6 (0.1)	(0.0, 0.3)	4517	0	(0.0, 0.1)
	Grade 4	4542	0	(0.0, 0.1)	4517	0	(0.0, 0.1)
	Diarrhea[f]						
	Any	4542	421 (9.3)	(8.4, 10.1)	4517	307 (6.8)	(6.1, 7.6)
	Mild	4542	344 (7.6)	(6.8, 8.4)	4517	245 (5.4)	(4.8, 6.1)
	Moderate	4542	69 (1.5)	(1.2, 1.9)	4517	57 (1.3)	(1.0, 1.6)
	Severe	4542	8 (0.2)	(0.1, 0.3)	4517	5 (0.1)	(0.0, 0.3)
	Grade 4	4542	0	(0.0, 0.1)	4517	0	(0.0, 0.1)
	New or worsened muscle pain[d]						
	Any	4542	1592 (35.1)	(33.7, 36.5)	4517	336 (7.4)	(6.7, 8.2)
	Mild	4542	670 (14.8)	(13.7, 15.8)	4517	215 (4.8)	(4.2, 5.4)
	Moderate	4542	840 (18.5)	(17.4, 19.7)	4517	117 (2.6)	(2.1, 3.1)

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

		Vaccine Group (as Administered)					
		BNT162b2 (30 µg)			Placebo		
Dose	**Systemic Event**	**N[a]**	**n[b] (%)**	**(95% CI[c])**	**N[a]**	**n[b] (%)**	**(95% CI[c])**
	Severe	4542	82 (1.8)	(1.4, 2.2)	4517	4 (0.1)	(0.0, 0.2)
	Grade 4	4542	0	(0.0, 0.1)	4517	0	(0.0, 0.1)
	New or worsened joint pain[d]						
	Any	4542	991 (21.8)	(20.6, 23.0)	4517	219 (4.8)	(4.2, 5.5)
	Mild	4542	474 (10.4)	(9.6, 11.4)	4517	126 (2.8)	(2.3, 3.3)
	Moderate	4542	481 (10.6)	(9.7, 11.5)	4517	88 (1.9)	(1.6, 2.4)
	Severe	4542	36 (0.8)	(0.6, 1.1)	4517	5 (0.1)	(0.0, 0.3)
	Grade 4	4542	0	(0.0, 0.1)	4517	0	(0.0, 0.1)
	Any systemic event[g]	4542	3237 (71.3)	(69.9, 72.6)	4517	1542 (34.1)	(32.8, 35.5)
	Use of antipyretic or pain medication[h]	4542	1901 (41.9)	(40.4, 43.3)	4517	490 (10.8)	(10.0, 11.8)
Any dose	Fever						
	≥38.0°C	4924	749 (15.2)	(14.2, 16.2)	4915	45 (0.9)	(0.7, 1.2)
	≥38.0°C to 38.4°C	4924	478 (9.7)	(8.9, 10.6)	4915	25 (0.5)	(0.3, 0.7)
	>38.4°C to 38.9°C	4924	219 (4.4)	(3.9, 5.1)	4915	12 (0.2)	(0.1, 0.4)
	>38.9°C to 40.0°C	4924	51 (1.0)	(0.8, 1.4)	4915	8 (0.2)	(0.1, 0.3)
	>40.0°C	4924	1 (0.0)	(0.0, 0.1)	4915	0	(0.0, 0.1)
	Fatigue[d]						
	Any	4924	3185 (64.7)	(63.3, 66.0)	4915	1758 (35.8)	(34.4, 37.1)
	Mild	4924	1157 (23.5)	(22.3, 24.7)	4915	956 (19.5)	(18.4, 20.6)
	Moderate	4924	1789 (36.3)	(35.0, 37.7)	4915	769 (15.6)	(14.6, 16.7)
	Severe	4924	238 (4.8)	(4.3, 5.5)	4915	33 (0.7)	(0.5, 0.9)
	Grade 4	4924	1 (0.0)	(0.0, 0.1)	4915	0	(0.0, 0.1)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 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])
	Headache[d]						
	Any	4924	2814 (57.1)	(55.8, 58.5)	4915	1717 (34.9)	(33.6, 36.3)
	Mild	4924	1458 (29.6)	(28.3, 30.9)	4915	1075 (21.9)	(20.7, 23.1)
	Moderate	4924	1223 (24.8)	(23.6, 26.1)	4915	593 (12.1)	(11.2, 13.0)
	Severe	4924	133 (2.7)	(2.3, 3.2)	4915	49 (1.0)	(0.7, 1.3)
	Grade 4	4924	0	(0.0, 0.1)	4915	0	(0.0, 0.1)
	Chills[d]						
	Any	4924	1707 (34.7)	(33.3, 36.0)	4915	380 (7.7)	(7.0, 8.5)
	Mild	4924	870 (17.7)	(16.6, 18.8)	4915	285 (5.8)	(5.2, 6.5)
	Moderate	4924	734 (14.9)	(13.9, 15.9)	4915	90 (1.8)	(1.5, 2.2)
	Severe	4924	103 (2.1)	(1.7, 2.5)	4915	5 (0.1)	(0.0, 0.2)
	Grade 4	4924	0	(0.0, 0.1)	4915	0	(0.0, 0.1)
	Vomiting[e]						
	Any	4924	110 (2.2)	(1.8, 2.7)	4915	74 (1.5)	(1.2, 1.9)
	Mild	4924	86 (1.7)	(1.4, 2.2)	4915	58 (1.2)	(0.9, 1.5)
	Moderate	4924	18 (0.4)	(0.2, 0.6)	4915	15 (0.3)	(0.2, 0.5)
	Severe	4924	6 (0.1)	(0.0, 0.3)	4915	1 (0.0)	(0.0, 0.1)
	Grade 4	4924	0	(0.0, 0.1)	4915	0	(0.0, 0.1)
	Diarrhea[f]						
	Any	4924	758 (15.4)	(14.4, 16.4)	4915	659 (13.4)	(12.5, 14.4)
	Mild	4924	603 (12.2)	(11.3, 13.2)	4915	524 (10.7)	(9.8, 11.6)
	Moderate	4924	140 (2.8)	(2.4, 3.3)	4915	128 (2.6)	(2.2, 3.1)
	Severe	4924	15 (0.3)	(0.2, 0.5)	4915	7 (0.1)	(0.1, 0.3)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 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])
	Grade 4	4924	0	(0.0, 0.1)	4915	0	(0.0, 0.1)
	New or worsened muscle pain[d]						
	Any	4924	1980 (40.2)	(38.8, 41.6)	4915	692 (14.1)	(13.1, 15.1)
	Mild	4924	826 (16.8)	(15.7, 17.8)	4915	442 (9.0)	(8.2, 9.8)
	Moderate	4924	1059 (21.5)	(20.4, 22.7)	4915	241 (4.9)	(4.3, 5.5)
	Severe	4924	95 (1.9)	(1.6, 2.4)	4915	9 (0.2)	(0.1, 0.3)
	Grade 4	4924	0	(0.0, 0.1)	4915	0	(0.0, 0.1)
	New or worsened joint pain[d]						
	Any	4924	1232 (25.0)	(23.8, 26.3)	4915	442 (9.0)	(8.2, 9.8)
	Mild	4924	586 (11.9)	(11.0, 12.8)	4915	259 (5.3)	(4.7, 5.9)
	Moderate	4924	602 (12.2)	(11.3, 13.2)	4915	176 (3.6)	(3.1, 4.1)
	Severe	4924	44 (0.9)	(0.7, 1.2)	4915	7 (0.1)	(0.1, 0.3)
	Grade 4	4924	0	(0.0, 0.1)	4915	0	(0.0, 0.1)
	Any systemic event[g]	4924	3878 (78.8)	(77.6, 79.9)	4915	2716 (55.3)	(53.9, 56.7)
	Use of antipyretic or pain medication[h]	4924	2301 (46.7)	(45.3, 48.1)	4915	924 (18.8)	(17.7, 19.9)

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. 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.

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.

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

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Phase 2/3 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])

visit or hospitalization for severe diarrhea.

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.

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

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 07APR2021 (17:15)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA1/adce s020 se 16 p3 saf

Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Requested Subgroup – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20172)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	9	2.332 (18559)	169	2.345 (18708)	94.6	(89.6, 97.6)
Age group (years)						
12 to 15	0	0.000 (14)	0	0.000 (14)	NE	(NE, NE)
16 to 17	0	0.003 (58)	1	0.003 (61)	100.0	(-3969.9, 100.0)
18 to 64	8	1.799 (14443)	149	1.811 (14566)	94.6	(89.1, 97.7)
65 to 74	1	0.424 (3239)	14	0.423 (3255)	92.9	(53.2, 99.8)
≥75	0	0.106 (805)	5	0.109 (812)	100.0	(-12.1, 100.0)
Race						
White	7	1.975 (15294)	153	1.990 (15473)	95.4	(90.3, 98.2)
Black or African American	0	0.187 (1758)	7	0.188 (1758)	100.0	(30.4, 100.0)
American Indian or Alaska native	0	0.011 (104)	1	0.010 (104)	100.0	(-3511.0, 100.0)
Asian	1	0.095 (796)	4	0.097 (808)	74.4	(-158.7, 99.5)
Native Hawaiian or other Pacific Islander	0	0.006 (50)	1	0.003 (29)	100.0	(-2112.1, 100.0)
Multiracial	1	0.047 (467)	1	0.042 (424)	10.4	(-6934.9, 98.9)
Not reported	0	0.010 (90)	2	0.013 (112)	100.0	(-581.6, 100.0)
Baseline SARS-CoV-2 status						
Positive[f]	1	0.056 (526)	1	0.060 (567)	-7.1	(-8309.9, 98.6)

Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Requested Subgroup – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20172)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Negative[g]	8	2.237 (17637)	164	2.242 (17720)	95.1	(90.1, 97.9)
Unknown	0	0.039 (396)	4	0.043 (421)	100.0	(-68.9, 100.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

a. N = number of subjects in the specified group.

b. n1 = Number of subjects meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of subjects at risk for the endpoint.

e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.

f. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.

g. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 23NOV2020 (16:39)
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