APPENDIX 6D TABLES SUPPORTING CLINICAL REACTOGENICITY DATA ON INDIVIDUALS PREVIOUSLY EXPOSED OR NOT TO SARS-COV-2

Reference to Section 16.3.3.2. Clinical Reactogenicity Data on Individuals Previously exposed or not to SARS-COV-2

Table 1. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	230	20 (8.7)	(5.4, 13.1)	123	10 (8.1)	(4.0, 14.4)
	Mild	230	18 (7.8)	(4.7, 12.1)	123	10 (8.1)	(4.0, 14.4)
	Moderate	230	2 (0.9)	(0.1, 3.1)	123	0	(0.0, 3.0)
	Severe	230	0	(0.0, 1.6)	123	0	(0.0, 3.0)
	Grade 4	230	0	(0.0, 1.6)	123	0	(0.0, 3.0)
	Swelling[d]						
	Any	230	11 (4.8)	(2.4, 8.4)	123	3 (2.4)	(0.5, 7.0)
	Mild	230	8 (3.5)	(1.5, 6.7)	123	3 (2.4)	(0.5, 7.0)
	Moderate	230	3 (1.3)	(0.3, 3.8)	123	0	(0.0, 3.0)
	Severe	230	0	(0.0, 1.6)	123	0	(0.0, 3.0)
	Grade 4	230	0	(0.0, 1.6)	123	0	(0.0, 3.0)
	Pain at the injection site[e]						
	Any	230	74 (32.2)	(26.2, 38.6)	122	21 (17.2)	(11.0, 25.1)
	Mild	230	64 (27.8)	(22.1, 34.1)	122	20 (16.4)	(10.3, 24.2)
	Moderate	230	10 (4.3)	(2.1, 7.9)	122	0	(0.0, 3.0)
	Severe	230	0	(0.0, 1.6)	122	1 (0.8)	(0.0, 4.5)
	Grade 4	230	0	(0.0, 1.6)	122	0	(0.0, 3.0)
	Any local reaction[f]	230	84 (36.5)	(30.3, 43.1)	123	28 (22.8)	(15.7, 31.2)
2	Redness[d]						
	Any	215	20 (9.3)	(5.8, 14.0)	117	6 (5.1)	(1.9, 10.8)
	Mild	215	16 (7.4)	(4.3, 11.8)	117	5 (4.3)	(1.4, 9.7)
	Moderate	215	4 (1.9)	(0.5, 4.7)	117	1 (0.9)	(0.0, 4.7)

Table 1. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Grade 4	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Swelling[d]						
	Any	215	15 (7.0)	(4.0, 11.2)	117	2 (1.7)	(0.2, 6.0)
	Mild	215	11 (5.1)	(2.6, 9.0)	117	1 (0.9)	(0.0, 4.7)
	Moderate	215	4 (1.9)	(0.5, 4.7)	117	1 (0.9)	(0.0, 4.7)
	Severe	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Grade 4	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Pain at the injection site[e]						
	Any	215	67 (31.2)	(25.0, 37.8)	117	16 (13.7)	(8.0, 21.3)
	Mild	215	58 (27.0)	(21.2, 33.4)	117	14 (12.0)	(6.7, 19.3)
	Moderate	215	9 (4.2)	(1.9, 7.8)	117	2 (1.7)	(0.2, 6.0)
	Severe	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Grade 4	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Any local reaction[f]	215	72 (33.5)	(27.2, 40.2)	117	20 (17.1)	(10.8, 25.2)
3	Redness[d]						
	Any	54	4 (7.4)	(2.1, 17.9)	33	0	(0.0, 10.6)
	Mild	54	4 (7.4)	(2.1, 17.9)	33	0	(0.0, 10.6)
	Moderate	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Severe	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Grade 4	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Swelling[d]						
	Any	54	1 (1.9)	(0.0, 9.9)	33	1 (3.0)	(0.1, 15.8)

Table 1. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	54	1 (1.9)	(0.0, 9.9)	33	1 (3.0)	(0.1, 15.8)
	Moderate	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Severe	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Grade 4	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Pain at the injection site[e]						
	Any	54	11 (20.4)	(10.6, 33.5)	33	3 (9.1)	(1.9, 24.3)
	Mild	54	7 (13.0)	(5.4, 24.9)	33	2 (6.1)	(0.7, 20.2)
	Moderate	54	4 (7.4)	(2.1, 17.9)	33	1 (3.0)	(0.1, 15.8)
	Severe	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Grade 4	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Any local reaction[f]	54	13 (24.1)	(13.5, 37.6)	33	3 (9.1)	(1.9, 24.3)
Any dose	Redness[d]						
	Any	231	35 (15.2)	(10.8, 20.4)	124	15 (12.1)	(6.9, 19.2)
	Mild	231	29 (12.6)	(8.6, 17.5)	124	14 (11.3)	(6.3, 18.2)
	Moderate	231	6 (2.6)	(1.0, 5.6)	124	1 (0.8)	(0.0, 4.4)
	Severe	231	0	(0.0, 1.6)	124	0	(0.0, 2.9)
	Grade 4	231	0	(0.0, 1.6)	124	0	(0.0, 2.9)
	Swelling[d]						
	Any	231	21 (9.1)	(5.7, 13.6)	124	6 (4.8)	(1.8, 10.2)
	Mild	231	16 (6.9)	(4.0, 11.0)	124	5 (4.0)	(1.3, 9.2)
	Moderate	231	5 (2.2)	(0.7, 5.0)	124	1 (0.8)	(0.0, 4.4)
	Severe	231	0	(0.0, 1.6)	124	0	(0.0, 2.9)
	Grade 4	231	0	(0.0, 1.6)	124	0	(0.0, 2.9)

Table 1. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Pain at the injection site[e]						
	Any	231	106 (45.9)	(39.3, 52.5)	124	28 (22.6)	(15.6, 31.0)
	Mild	231	88 (38.1)	(31.8, 44.7)	124	25 (20.2)	(13.5, 28.3)
	Moderate	231	18 (7.8)	(4.7, 12.0)	124	2 (1.6)	(0.2, 5.7)
	Severe	231	0	(0.0, 1.6)	124	1 (0.8)	(0.0, 4.4)
	Grade 4	231	0	(0.0, 1.6)	124	0	(0.0, 2.9)
	Any local reaction[f]	231	118 (51.1)	(44.4, 57.7)	124	37 (29.8)	(22.0, 38.7)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Reactions were collected in the e-diary and unscheduled clinical assessments from Day 1 through Day 7 after each vaccination.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
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.
a. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: ≥0.5 to 2.0 cm; moderate: >2.0 to 7.0 cm; severe: >7.0 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 ≥0.5 cm, any swelling ≥0.5 cm, or any pain at the injection site.
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Table 2. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	1590	140 (8.8)	(7.5, 10.3)	779	67 (8.6)	(6.7, 10.8)
	Mild	1590	119 (7.5)	(6.2, 8.9)	779	57 (7.3)	(5.6, 9.4)
	Moderate	1590	20 (1.3)	(0.8, 1.9)	779	9 (1.2)	(0.5, 2.2)
	Severe	1590	1 (0.1)	(0.0, 0.3)	779	1 (0.1)	(0.0, 0.7)
	Grade 4	1590	0	(0.0, 0.2)	779	0	(0.0, 0.5)
	Swelling[d]						
	Any	1590	56 (3.5)	(2.7, 4.5)	779	23 (3.0)	(1.9, 4.4)
	Mild	1590	51 (3.2)	(2.4, 4.2)	779	18 (2.3)	(1.4, 3.6)
	Moderate	1590	5 (0.3)	(0.1, 0.7)	779	5 (0.6)	(0.2, 1.5)
	Severe	1590	0	(0.0, 0.2)	779	0	(0.0, 0.5)
	Grade 4	1590	0	(0.0, 0.2)	779	0	(0.0, 0.5)
	Pain at the injection site[e]						
	Any	1579	484 (30.7)	(28.4, 33.0)	776	165 (21.3)	(18.4, 24.3)
	Mild	1579	458 (29.0)	(26.8, 31.3)	776	158 (20.4)	(17.6, 23.4)
	Moderate	1579	26 (1.6)	(1.1, 2.4)	776	7 (0.9)	(0.4, 1.8)
	Severe	1579	0	(0.0, 0.2)	776	0	(0.0, 0.5)
	Grade 4	1579	0	(0.0, 0.2)	776	0	(0.0, 0.5)
	Any local reaction[f]	1590	563 (35.4)	(33.1, 37.8)	779	201 (25.8)	(22.8, 29.0)
2	Redness[d]						
	Any	1559	181 (11.6)	(10.1, 13.3)	755	44 (5.8)	(4.3, 7.7)
	Mild	1559	153 (9.8)	(8.4, 11.4)	755	38 (5.0)	(3.6, 6.8)
	Moderate	1559	27 (1.7)	(1.1, 2.5)	755	6 (0.8)	(0.3, 1.7)

Table 2. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	1559	1 (0.1)	(0.0, 0.4)	755	0	(0.0, 0.5)
	Grade 4	1559	0	(0.0, 0.2)	755	0	(0.0, 0.5)
	Swelling[d]						
	Any	1559	87 (5.6)	(4.5, 6.8)	755	16 (2.1)	(1.2, 3.4)
	Mild	1559	70 (4.5)	(3.5, 5.6)	755	15 (2.0)	(1.1, 3.3)
	Moderate	1559	17 (1.1)	(0.6, 1.7)	755	1 (0.1)	(0.0, 0.7)
	Severe	1559	0	(0.0, 0.2)	755	0	(0.0, 0.5)
	Grade 4	1559	0	(0.0, 0.2)	755	0	(0.0, 0.5)
	Pain at the injection site[e]						
	Any	1552	482 (31.1)	(28.8, 33.4)	754	161 (21.4)	(18.5, 24.5)
	Mild	1552	455 (29.3)	(27.1, 31.7)	754	154 (20.4)	(17.6, 23.5)
	Moderate	1552	27 (1.7)	(1.1, 2.5)	754	6 (0.8)	(0.3, 1.7)
	Severe	1552	0	(0.0, 0.2)	754	1 (0.1)	(0.0, 0.7)
	Grade 4	1552	0	(0.0, 0.2)	754	0	(0.0, 0.5)
	Any local reaction[f]	1559	571 (36.6)	(34.2, 39.1)	755	184 (24.4)	(21.3, 27.6)
3	Redness[d]						
	Any	498	56 (11.2)	(8.6, 14.4)	226	9 (4.0)	(1.8, 7.4)
	Mild	498	49 (9.8)	(7.4, 12.8)	226	7 (3.1)	(1.3, 6.3)
	Moderate	498	7 (1.4)	(0.6, 2.9)	226	2 (0.9)	(0.1, 3.2)
	Severe	498	0	(0.0, 0.7)	226	0	(0.0, 1.6)
	Grade 4	498	0	(0.0, 0.7)	226	0	(0.0, 1.6)
	Swelling[d]						
	Any	498	16 (3.2)	(1.8, 5.2)	226	2 (0.9)	(0.1, 3.2)

Table 2. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	498	15 (3.0)	(1.7, 4.9)	226	2 (0.9)	(0.1, 3.2)
	Moderate	498	1 (0.2)	(0.0, 1.1)	226	0	(0.0, 1.6)
	Severe	498	0	(0.0, 0.7)	226	0	(0.0, 1.6)
	Grade 4	498	0	(0.0, 0.7)	226	0	(0.0, 1.6)
	Pain at the injection site[e]						
	Any	493	135 (27.4)	(23.5, 31.5)	226	32 (14.2)	(9.9, 19.4)
	Mild	493	123 (24.9)	(21.2, 29.0)	226	31 (13.7)	(9.5, 18.9)
	Moderate	493	12 (2.4)	(1.3, 4.2)	226	1 (0.4)	(0.0, 2.4)
	Severe	493	0	(0.0, 0.7)	226	0	(0.0, 1.6)
	Grade 4	493	0	(0.0, 0.7)	226	0	(0.0, 1.6)
	Any local reaction[f]	498	161 (32.3)	(28.2, 36.6)	226	38 (16.8)	(12.2, 22.3)
Any dose	Redness[d]						
	Any	1597	310 (19.4)	(17.5, 21.4)	782	102 (13.0)	(10.8, 15.6)
	Mild	1597	256 (16.0)	(14.3, 17.9)	782	85 (10.9)	(8.8, 13.3)
	Moderate	1597	52 (3.3)	(2.4, 4.2)	782	16 (2.0)	(1.2, 3.3)
	Severe	1597	2 (0.1)	(0.0, 0.5)	782	1 (0.1)	(0.0, 0.7)
	Grade 4	1597	0	(0.0, 0.2)	782	0	(0.0, 0.5)
	Swelling[d]						
	Any	1597	133 (8.3)	(7.0, 9.8)	782	36 (4.6)	(3.2, 6.3)
	Mild	1597	112 (7.0)	(5.8, 8.4)	782	31 (4.0)	(2.7, 5.6)
	Moderate	1597	21 (1.3)	(0.8, 2.0)	782	5 (0.6)	(0.2, 1.5)
	Severe	1597	0	(0.0, 0.2)	782	0	(0.0, 0.5)
	Grade 4	1597	0	(0.0, 0.2)	782	0	(0.0, 0.5)

Table 2. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Pain at the injection site[e]						
	Any	1590	750 (47.2)	(44.7, 49.7)	780	266 (34.1)	(30.8, 37.5)
	Mild	1590	690 (43.4)	(40.9, 45.9)	780	252 (32.3)	(29.0, 35.7)
	Moderate	1590	60 (3.8)	(2.9, 4.8)	780	13 (1.7)	(0.9, 2.8)
	Severe	1590	0	(0.0, 0.2)	780	1 (0.1)	(0.0, 0.7)
	Grade 4	1590	0	(0.0, 0.2)	780	0	(0.0, 0.5)
	Any local reaction[f]	1597	860 (53.9)	(51.4, 56.3)	782	310 (39.6)	(36.2, 43.2)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Reactions were collected in the e-diary and unscheduled clinical assessments from Day 1 through Day 7 after each vaccination.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
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.
a. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: ≥0.5 to 2.0 cm; moderate: >2.0 to 7.0 cm; severe: >7.0 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 ≥0.5 cm, any swelling ≥0.5 cm, or any pain at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 12MAY2022 (06:32) Source Data: adfacevd Table Generation: 12MAY2022 (22:47)
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Table 3. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	≥38.0°C	229	8 (3.5)	(1.5, 6.8)	123	9 (7.3)	(3.4, 13.4)
	≥38.0°C to 38.4°C	229	4 (1.7)	(0.5, 4.4)	123	3 (2.4)	(0.5, 7.0)
	>38.4°C to 38.9°C	229	2 (0.9)	(0.1, 3.1)	123	6 (4.9)	(1.8, 10.3)
	>38.9°C to 40.0°C	229	1 (0.4)	(0.0, 2.4)	123	0	(0.0, 3.0)
	>40.0°C	229	1 (0.4)	(0.0, 2.4)	123	0	(0.0, 3.0)
	Fatigue[d]						
	Any	230	56 (24.3)	(18.9, 30.4)	122	34 (27.9)	(20.1, 36.7)
	Mild	230	34 (14.8)	(10.5, 20.0)	122	16 (13.1)	(7.7, 20.4)
	Moderate	230	19 (8.3)	(5.0, 12.6)	122	17 (13.9)	(8.3, 21.4)
	Severe	230	3 (1.3)	(0.3, 3.8)	122	1 (0.8)	(0.0, 4.5)
	Grade 4	230	0	(0.0, 1.6)	122	0	(0.0, 3.0)
	Headache[d]						
	Any	230	16 (7.0)	(4.0, 11.1)	122	5 (4.1)	(1.3, 9.3)
	Mild	230	11 (4.8)	(2.4, 8.4)	122	2 (1.6)	(0.2, 5.8)
	Moderate	230	5 (2.2)	(0.7, 5.0)	122	3 (2.5)	(0.5, 7.0)
	Severe	230	0	(0.0, 1.6)	122	0	(0.0, 3.0)
	Grade 4	230	0	(0.0, 1.6)	122	0	(0.0, 3.0)
	Chills[d]						
	Any	230	8 (3.5)	(1.5, 6.7)	122	3 (2.5)	(0.5, 7.0)
	Mild	230	5 (2.2)	(0.7, 5.0)	122	2 (1.6)	(0.2, 5.8)
	Moderate	230	2 (0.9)	(0.1, 3.1)	122	1 (0.8)	(0.0, 4.5)
	Severe	230	1 (0.4)	(0.0, 2.4)	122	0	(0.0, 3.0)
	Grade 4	230	0	(0.0, 1.6)	122	0	(0.0, 3.0)

Table 3. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Vomiting[e]						
	Any	230	10 (4.3)	(2.1, 7.9)	122	7 (5.7)	(2.3, 11.5)
	Mild	230	7 (3.0)	(1.2, 6.2)	122	4 (3.3)	(0.9, 8.2)
	Moderate	230	3 (1.3)	(0.3, 3.8)	122	3 (2.5)	(0.5, 7.0)
	Severe	230	0	(0.0, 1.6)	122	0	(0.0, 3.0)
	Grade 4	230	0	(0.0, 1.6)	122	0	(0.0, 3.0)
	Diarrhea[f]						
	Any	230	22 (9.6)	(6.1, 14.1)	122	12 (9.8)	(5.2, 16.6)
	Mild	230	20 (8.7)	(5.4, 13.1)	122	9 (7.4)	(3.4, 13.5)
	Moderate	230	2 (0.9)	(0.1, 3.1)	122	3 (2.5)	(0.5, 7.0)
	Severe	230	0	(0.0, 1.6)	122	0	(0.0, 3.0)
	Grade 4	230	0	(0.0, 1.6)	122	0	(0.0, 3.0)
	New or worsened muscle pain[d]						
	Any	230	3 (1.3)	(0.3, 3.8)	122	3 (2.5)	(0.5, 7.0)
	Mild	230	2 (0.9)	(0.1, 3.1)	122	1 (0.8)	(0.0, 4.5)
	Moderate	230	1 (0.4)	(0.0, 2.4)	122	2 (1.6)	(0.2, 5.8)
	Severe	230	0	(0.0, 1.6)	122	0	(0.0, 3.0)
	Grade 4	230	0	(0.0, 1.6)	122	0	(0.0, 3.0)
	New or worsened joint pain[d]						
	Any	230	1 (0.4)	(0.0, 2.4)	122	4 (3.3)	(0.9, 8.2)
	Mild	230	1 (0.4)	(0.0, 2.4)	122	2 (1.6)	(0.2, 5.8)
	Moderate	230	0	(0.0, 1.6)	122	2 (1.6)	(0.2, 5.8)
	Severe	230	0	(0.0, 1.6)	122	0	(0.0, 3.0)
	Grade 4	230	0	(0.0, 1.6)	122	0	(0.0, 3.0)

Table 3. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any systemic event[g]	230	83 (36.1)	(29.9, 42.7)	123	42 (34.1)	(25.8, 43.2)
	Use of antipyretic or pain medication[h]	230	25 (10.9)	(7.2, 15.6)	123	15 (12.2)	(7.0, 19.3)
2	Fever						
	≥38.0°C	215	14 (6.5)	(3.6, 10.7)	117	10 (8.5)	(4.2, 15.2)
	≥38.0°C to 38.4°C	215	8 (3.7)	(1.6, 7.2)	117	2 (1.7)	(0.2, 6.0)
	>38.4°C to 38.9°C	215	3 (1.4)	(0.3, 4.0)	117	5 (4.3)	(1.4, 9.7)
	>38.9°C to 40.0°C	215	3 (1.4)	(0.3, 4.0)	117	3 (2.6)	(0.5, 7.3)
	>40.0°C	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Fatigue[d]						
	Any	215	40 (18.6)	(13.6, 24.5)	117	22 (18.8)	(12.2, 27.1)
	Mild	215	20 (9.3)	(5.8, 14.0)	117	11 (9.4)	(4.8, 16.2)
	Moderate	215	18 (8.4)	(5.0, 12.9)	117	11 (9.4)	(4.8, 16.2)
	Severe	215	2 (0.9)	(0.1, 3.3)	117	0	(0.0, 3.1)
	Grade 4	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Headache[d]						
	Any	215	11 (5.1)	(2.6, 9.0)	117	7 (6.0)	(2.4, 11.9)
	Mild	215	7 (3.3)	(1.3, 6.6)	117	4 (3.4)	(0.9, 8.5)
	Moderate	215	4 (1.9)	(0.5, 4.7)	117	2 (1.7)	(0.2, 6.0)
	Severe	215	0	(0.0, 1.7)	117	1 (0.9)	(0.0, 4.7)
	Grade 4	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Chills[d]						
	Any	215	6 (2.8)	(1.0, 6.0)	117	4 (3.4)	(0.9, 8.5)
	Mild	215	3 (1.4)	(0.3, 4.0)	117	0	(0.0, 3.1)

Table 3. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	215	3 (1.4)	(0.3, 4.0)	117	4 (3.4)	(0.9, 8.5)
	Severe	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Grade 4	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Vomiting[e]						
	Any	215	8 (3.7)	(1.6, 7.2)	117	6 (5.1)	(1.9, 10.8)
	Mild	215	7 (3.3)	(1.3, 6.6)	117	5 (4.3)	(1.4, 9.7)
	Moderate	215	1 (0.5)	(0.0, 2.6)	117	1 (0.9)	(0.0, 4.7)
	Severe	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Grade 4	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Diarrhea[f]						
	Any	215	9 (4.2)	(1.9, 7.8)	117	9 (7.7)	(3.6, 14.1)
	Mild	215	9 (4.2)	(1.9, 7.8)	117	6 (5.1)	(1.9, 10.8)
	Moderate	215	0	(0.0, 1.7)	117	3 (2.6)	(0.5, 7.3)
	Severe	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Grade 4	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	New or worsened muscle pain[d]						
	Any	215	4 (1.9)	(0.5, 4.7)	117	1 (0.9)	(0.0, 4.7)
	Mild	215	4 (1.9)	(0.5, 4.7)	117	0	(0.0, 3.1)
	Moderate	215	0	(0.0, 1.7)	117	1 (0.9)	(0.0, 4.7)
	Severe	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Grade 4	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	New or worsened joint pain[d]						
	Any	215	3 (1.4)	(0.3, 4.0)	117	2 (1.7)	(0.2, 6.0)
	Mild	215	3 (1.4)	(0.3, 4.0)	117	1 (0.9)	(0.0, 4.7)

Table 3. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	215	0	(0.0, 1.7)	117	1 (0.9)	(0.0, 4.7)
	Severe	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Grade 4	215	0	(0.0, 1.7)	117	0	(0.0, 3.1)
	Any systemic event[g]	215	55 (25.6)	(19.9, 32.0)	117	36 (30.8)	(22.6, 40.0)
	Use of antipyretic or pain medication[h]	215	29 (13.5)	(9.2, 18.8)	117	13 (11.1)	(6.1, 18.3)
3	Fever						
	≥38.0°C	54	2 (3.7)	(0.5, 12.7)	33	1 (3.0)	(0.1, 15.8)
	≥38.0°C to 38.4°C	54	2 (3.7)	(0.5, 12.7)	33	0	(0.0, 10.6)
	>38.4°C to 38.9°C	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	>38.9°C to 40.0°C	54	0	(0.0, 6.6)	33	1 (3.0)	(0.1, 15.8)
	>40.0°C	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Fatigue[d]						
	Any	54	11 (20.4)	(10.6, 33.5)	33	5 (15.2)	(5.1, 31.9)
	Mild	54	5 (9.3)	(3.1, 20.3)	33	2 (6.1)	(0.7, 20.2)
	Moderate	54	5 (9.3)	(3.1, 20.3)	33	3 (9.1)	(1.9, 24.3)
	Severe	54	1 (1.9)	(0.0, 9.9)	33	0	(0.0, 10.6)
	Grade 4	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Headache[d]						
	Any	54	3 (5.6)	(1.2, 15.4)	33	0	(0.0, 10.6)
	Mild	54	2 (3.7)	(0.5, 12.7)	33	0	(0.0, 10.6)
	Moderate	54	1 (1.9)	(0.0, 9.9)	33	0	(0.0, 10.6)
	Severe	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Grade 4	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)

Table 3. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Chills[d]						
	Any	54	1 (1.9)	(0.0, 9.9)	33	1 (3.0)	(0.1, 15.8)
	Mild	54	1 (1.9)	(0.0, 9.9)	33	1 (3.0)	(0.1, 15.8)
	Moderate	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Severe	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Grade 4	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Vomiting[e]						
	Any	54	1 (1.9)	(0.0, 9.9)	33	0	(0.0, 10.6)
	Mild	54	1 (1.9)	(0.0, 9.9)	33	0	(0.0, 10.6)
	Moderate	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Severe	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Grade 4	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Diarrhea[f]						
	Any	54	5 (9.3)	(3.1, 20.3)	33	2 (6.1)	(0.7, 20.2)
	Mild	54	4 (7.4)	(2.1, 17.9)	33	1 (3.0)	(0.1, 15.8)
	Moderate	54	1 (1.9)	(0.0, 9.9)	33	1 (3.0)	(0.1, 15.8)
	Severe	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Grade 4	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	New or worsened muscle pain[d]						
	Any	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Mild	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Moderate	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Severe	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Grade 4	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)

Table 3. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	New or worsened joint pain[d]						
	Any	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Mild	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Moderate	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Severe	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Grade 4	54	0	(0.0, 6.6)	33	0	(0.0, 10.6)
	Any systemic event[g]	54	13 (24.1)	(13.5, 37.6)	33	8 (24.2)	(11.1, 42.3)
	Use of antipyretic or pain medication[h]	54	7 (13.0)	(5.4, 24.9)	33	2 (6.1)	(0.7, 20.2)
Any dose	Fever						
	≥38.0°C	230	23 (10.0)	(6.4, 14.6)	124	19 (15.3)	(9.5, 22.9)
	≥38.0°C to 38.4°C	230	13 (5.7)	(3.0, 9.5)	124	4 (3.2)	(0.9, 8.1)
	>38.4°C to 38.9°C	230	5 (2.2)	(0.7, 5.0)	124	11 (8.9)	(4.5, 15.3)
	>38.9°C to 40.0°C	230	4 (1.7)	(0.5, 4.4)	124	4 (3.2)	(0.9, 8.1)
	>40.0°C	230	1 (0.4)	(0.0, 2.4)	124	0	(0.0, 2.9)
	Fatigue[d]						
	Any	231	82 (35.5)	(29.3, 42.0)	124	48 (38.7)	(30.1, 47.9)
	Mild	231	43 (18.6)	(13.8, 24.2)	124	22 (17.7)	(11.5, 25.6)
	Moderate	231	33 (14.3)	(10.0, 19.5)	124	25 (20.2)	(13.5, 28.3)
	Severe	231	6 (2.6)	(1.0, 5.6)	124	1 (0.8)	(0.0, 4.4)
	Grade 4	231	0	(0.0, 1.6)	124	0	(0.0, 2.9)
	Headache[d]						
	Any	231	24 (10.4)	(6.8, 15.1)	124	10 (8.1)	(3.9, 14.3)
	Mild	231	14 (6.1)	(3.4, 10.0)	124	4 (3.2)	(0.9, 8.1)

Table 3. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	231	10 (4.3)	(2.1, 7.8)	124	5 (4.0)	(1.3, 9.2)
	Severe	231	0	(0.0, 1.6)	124	1 (0.8)	(0.0, 4.4)
	Grade 4	231	0	(0.0, 1.6)	124	0	(0.0, 2.9)
	Chills[d]						
	Any	231	14 (6.1)	(3.4, 10.0)	124	8 (6.5)	(2.8, 12.3)
	Mild	231	8 (3.5)	(1.5, 6.7)	124	3 (2.4)	(0.5, 6.9)
	Moderate	231	5 (2.2)	(0.7, 5.0)	124	5 (4.0)	(1.3, 9.2)
	Severe	231	1 (0.4)	(0.0, 2.4)	124	0	(0.0, 2.9)
	Grade 4	231	0	(0.0, 1.6)	124	0	(0.0, 2.9)
	Vomiting[e]						
	Any	231	19 (8.2)	(5.0, 12.5)	124	13 (10.5)	(5.7, 17.3)
	Mild	231	15 (6.5)	(3.7, 10.5)	124	9 (7.3)	(3.4, 13.3)
	Moderate	231	4 (1.7)	(0.5, 4.4)	124	4 (3.2)	(0.9, 8.1)
	Severe	231	0	(0.0, 1.6)	124	0	(0.0, 2.9)
	Grade 4	231	0	(0.0, 1.6)	124	0	(0.0, 2.9)
	Diarrhea[f]						
	Any	231	33 (14.3)	(10.0, 19.5)	124	19 (15.3)	(9.5, 22.9)
	Mild	231	30 (13.0)	(8.9, 18.0)	124	13 (10.5)	(5.7, 17.3)
	Moderate	231	3 (1.3)	(0.3, 3.7)	124	6 (4.8)	(1.8, 10.2)
	Severe	231	0	(0.0, 1.6)	124	0	(0.0, 2.9)
	Grade 4	231	0	(0.0, 1.6)	124	0	(0.0, 2.9)
	New or worsened muscle pain[d]						
	Any	231	7 (3.0)	(1.2, 6.1)	124	4 (3.2)	(0.9, 8.1)
	Mild	231	6 (2.6)	(1.0, 5.6)	124	1 (0.8)	(0.0, 4.4)

Table 3. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	231	1 (0.4)	(0.0, 2.4)	124	3 (2.4)	(0.5, 6.9)
	Severe	231	0	(0.0, 1.6)	124	0	(0.0, 2.9)
	Grade 4	231	0	(0.0, 1.6)	124	0	(0.0, 2.9)
	New or worsened joint pain[d]						
	Any	231	4 (1.7)	(0.5, 4.4)	124	5 (4.0)	(1.3, 9.2)
	Mild	231	4 (1.7)	(0.5, 4.4)	124	2 (1.6)	(0.2, 5.7)
	Moderate	231	0	(0.0, 1.6)	124	3 (2.4)	(0.5, 6.9)
	Severe	231	0	(0.0, 1.6)	124	0	(0.0, 2.9)
	Grade 4	231	0	(0.0, 1.6)	124	0	(0.0, 2.9)
	Any systemic event[g]	231	110 (47.6)	(41.0, 54.3)	124	62 (50.0)	(40.9, 59.1)
	Use of antipyretic or pain medication[h]	231	50 (21.6)	(16.5, 27.5)	124	27 (21.8)	(14.9, 30.1)

Table 3. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Events and use of antipyretic or pain medication were collected in the e-diary and unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person.
Note: Participants 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.
a. N = number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants 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 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: 12MAY2022 (08:23) Source Data: adfacevd Table Generation: 13MAY2022 (07:04)
(Cutoff Date: 29APR2022, Snapshot Date: 11MAY2022) Output File: ./nda2_ubped/C4591007_6M_LT5Y_SAF_IMM_EUA_MAY2022/adce_s020_se_p2_bs_5

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	≥38.0°C	1590	87 (5.5)	(4.4, 6.7)	779	38 (4.9)	(3.5, 6.6)
	≥38.0°C to 38.4°C	1590	53 (3.3)	(2.5, 4.3)	779	20 (2.6)	(1.6, 3.9)
	>38.4°C to 38.9°C	1590	22 (1.4)	(0.9, 2.1)	779	10 (1.3)	(0.6, 2.3)
	>38.9°C to 40.0°C	1590	12 (0.8)	(0.4, 1.3)	779	8 (1.0)	(0.4, 2.0)
	>40.0°C	1590	0	(0.0, 0.2)	779	0	(0.0, 0.5)
	Fatigue[d]						
	Any	1578	479 (30.4)	(28.1, 32.7)	776	241 (31.1)	(27.8, 34.4)
	Mild	1578	298 (18.9)	(17.0, 20.9)	776	159 (20.5)	(17.7, 23.5)
	Moderate	1578	178 (11.3)	(9.8, 12.9)	776	78 (10.1)	(8.0, 12.4)
	Severe	1578	3 (0.2)	(0.0, 0.6)	776	4 (0.5)	(0.1, 1.3)
	Grade 4	1578	0	(0.0, 0.2)	776	0	(0.0, 0.5)
	Headache[d]						
	Any	1578	65 (4.1)	(3.2, 5.2)	776	39 (5.0)	(3.6, 6.8)
	Mild	1578	52 (3.3)	(2.5, 4.3)	776	33 (4.3)	(2.9, 5.9)
	Moderate	1578	13 (0.8)	(0.4, 1.4)	776	5 (0.6)	(0.2, 1.5)
	Severe	1578	0	(0.0, 0.2)	776	1 (0.1)	(0.0, 0.7)
	Grade 4	1578	0	(0.0, 0.2)	776	0	(0.0, 0.5)
	Chills[d]						
	Any	1578	33 (2.1)	(1.4, 2.9)	776	19 (2.4)	(1.5, 3.8)
	Mild	1578	23 (1.5)	(0.9, 2.2)	776	14 (1.8)	(1.0, 3.0)
	Moderate	1578	8 (0.5)	(0.2, 1.0)	776	5 (0.6)	(0.2, 1.5)
	Severe	1578	2 (0.1)	(0.0, 0.5)	776	0	(0.0, 0.5)
	Grade 4	1578	0	(0.0, 0.2)	776	0	(0.0, 0.5)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Vomiting[e]						
	Any	1578	44 (2.8)	(2.0, 3.7)	776	17 (2.2)	(1.3, 3.5)
	Mild	1578	37 (2.3)	(1.7, 3.2)	776	10 (1.3)	(0.6, 2.4)
	Moderate	1578	7 (0.4)	(0.2, 0.9)	776	7 (0.9)	(0.4, 1.8)
	Severe	1578	0	(0.0, 0.2)	776	0	(0.0, 0.5)
	Grade 4	1578	0	(0.0, 0.2)	776	0	(0.0, 0.5)
	Diarrhea[f]						
	Any	1578	117 (7.4)	(6.2, 8.8)	776	60 (7.7)	(6.0, 9.8)
	Mild	1578	110 (7.0)	(5.8, 8.3)	776	55 (7.1)	(5.4, 9.1)
	Moderate	1578	7 (0.4)	(0.2, 0.9)	776	5 (0.6)	(0.2, 1.5)
	Severe	1578	0	(0.0, 0.2)	776	0	(0.0, 0.5)
	Grade 4	1578	0	(0.0, 0.2)	776	0	(0.0, 0.5)
	New or worsened muscle pain[d]						
	Any	1578	40 (2.5)	(1.8, 3.4)	776	11 (1.4)	(0.7, 2.5)
	Mild	1578	31 (2.0)	(1.3, 2.8)	776	11 (1.4)	(0.7, 2.5)
	Moderate	1578	8 (0.5)	(0.2, 1.0)	776	0	(0.0, 0.5)
	Severe	1578	1 (0.1)	(0.0, 0.4)	776	0	(0.0, 0.5)
	Grade 4	1578	0	(0.0, 0.2)	776	0	(0.0, 0.5)
	New or worsened joint pain[d]						
	Any	1578	13 (0.8)	(0.4, 1.4)	776	13 (1.7)	(0.9, 2.8)
	Mild	1578	11 (0.7)	(0.3, 1.2)	776	10 (1.3)	(0.6, 2.4)
	Moderate	1578	2 (0.1)	(0.0, 0.5)	776	3 (0.4)	(0.1, 1.1)
	Severe	1578	0	(0.0, 0.2)	776	0	(0.0, 0.5)
	Grade 4	1578	0	(0.0, 0.2)	776	0	(0.0, 0.5)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any systemic event[g]	1590	606 (38.1)	(35.7, 40.6)	779	310 (39.8)	(36.3, 43.3)
	Use of antipyretic or pain medication[b]	1590	172 (10.8)	(9.3, 12.4)	779	67 (8.6)	(6.7, 10.8)
2	Fever						
	≥38.0°C	1559	74 (4.7)	(3.7, 5.9)	755	36 (4.8)	(3.4, 6.5)
	≥38.0°C to 38.4°C	1559	33 (2.1)	(1.5, 3.0)	755	15 (2.0)	(1.1, 3.3)
	>38.4°C to 38.9°C	1559	23 (1.5)	(0.9, 2.2)	755	16 (2.1)	(1.2, 3.4)
	>38.9°C to 40.0°C	1559	16 (1.0)	(0.6, 1.7)	755	5 (0.7)	(0.2, 1.5)
	>40.0°C	1559	2 (0.1)	(0.0, 0.5)	755	0	(0.0, 0.5)
	Fatigue[d]						
	Any	1552	413 (26.6)	(24.4, 28.9)	754	177 (23.5)	(20.5, 26.7)
	Mild	1552	245 (15.8)	(14.0, 17.7)	754	108 (14.3)	(11.9, 17.0)
	Moderate	1552	162 (10.4)	(9.0, 12.1)	754	66 (8.8)	(6.8, 11.0)
	Severe	1552	6 (0.4)	(0.1, 0.8)	754	3 (0.4)	(0.1, 1.2)
	Grade 4	1552	0	(0.0, 0.2)	754	0	(0.0, 0.5)
	Headache[d]						
	Any	1552	69 (4.4)	(3.5, 5.6)	754	29 (3.8)	(2.6, 5.5)
	Mild	1552	55 (3.5)	(2.7, 4.6)	754	19 (2.5)	(1.5, 3.9)
	Moderate	1552	14 (0.9)	(0.5, 1.5)	754	10 (1.3)	(0.6, 2.4)
	Severe	1552	0	(0.0, 0.2)	754	0	(0.0, 0.5)
	Grade 4	1552	0	(0.0, 0.2)	754	0	(0.0, 0.5)
	Chills[d]						
	Any	1552	47 (3.0)	(2.2, 4.0)	754	18 (2.4)	(1.4, 3.7)
	Mild	1552	32 (2.1)	(1.4, 2.9)	754	16 (2.1)	(1.2, 3.4)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	1552	15 (1.0)	(0.5, 1.6)	754	2 (0.3)	(0.0, 1.0)
	Severe	1552	0	(0.0, 0.2)	754	0	(0.0, 0.5)
	Grade 4	1552	0	(0.0, 0.2)	754	0	(0.0, 0.5)
	Vomiting[e]						
	Any	1552	52 (3.4)	(2.5, 4.4)	754	22 (2.9)	(1.8, 4.4)
	Mild	1552	47 (3.0)	(2.2, 4.0)	754	20 (2.7)	(1.6, 4.1)
	Moderate	1552	5 (0.3)	(0.1, 0.8)	754	2 (0.3)	(0.0, 1.0)
	Severe	1552	0	(0.0, 0.2)	754	0	(0.0, 0.5)
	Grade 4	1552	0	(0.0, 0.2)	754	0	(0.0, 0.5)
	Diarrhea[f]						
	Any	1552	108 (7.0)	(5.7, 8.3)	754	55 (7.3)	(5.5, 9.4)
	Mild	1552	95 (6.1)	(5.0, 7.4)	754	51 (6.8)	(5.1, 8.8)
	Moderate	1552	12 (0.8)	(0.4, 1.3)	754	4 (0.5)	(0.1, 1.4)
	Severe	1552	1 (0.1)	(0.0, 0.4)	754	0	(0.0, 0.5)
	Grade 4	1552	0	(0.0, 0.2)	754	0	(0.0, 0.5)
	New or worsened muscle pain[d]						
	Any	1552	42 (2.7)	(2.0, 3.6)	754	20 (2.7)	(1.6, 4.1)
	Mild	1552	29 (1.9)	(1.3, 2.7)	754	17 (2.3)	(1.3, 3.6)
	Moderate	1552	13 (0.8)	(0.4, 1.4)	754	3 (0.4)	(0.1, 1.2)
	Severe	1552	0	(0.0, 0.2)	754	0	(0.0, 0.5)
	Grade 4	1552	0	(0.0, 0.2)	754	0	(0.0, 0.5)
	New or worsened joint pain[d]						
	Any	1552	21 (1.4)	(0.8, 2.1)	754	7 (0.9)	(0.4, 1.9)
	Mild	1552	15 (1.0)	(0.5, 1.6)	754	5 (0.7)	(0.2, 1.5)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	1552	6 (0.4)	(0.1, 0.8)	754	2 (0.3)	(0.0, 1.0)
	Severe	1552	0	(0.0, 0.2)	754	0	(0.0, 0.5)
	Grade 4	1552	0	(0.0, 0.2)	754	0	(0.0, 0.5)
	Any systemic event[g]	1559	540 (34.6)	(32.3, 37.1)	755	244 (32.3)	(29.0, 35.8)
	Use of antipyretic or pain medication[h]	1559	147 (9.4)	(8.0, 11.0)	755	61 (8.1)	(6.2, 10.3)
3	Fever						
	≥38.0°C	498	26 (5.2)	(3.4, 7.6)	226	10 (4.4)	(2.1, 8.0)
	≥38.0°C to 38.4°C	498	14 (2.8)	(1.5, 4.7)	226	4 (1.8)	(0.5, 4.5)
	>38.4°C to 38.9°C	498	8 (1.6)	(0.7, 3.1)	226	4 (1.8)	(0.5, 4.5)
	>38.9°C to 40.0°C	498	4 (0.8)	(0.2, 2.0)	226	2 (0.9)	(0.1, 3.2)
	>40.0°C	498	0	(0.0, 0.7)	226	0	(0.0, 1.6)
	Fatigue[d]						
	Any	493	123 (24.9)	(21.2, 29.0)	226	52 (23.0)	(17.7, 29.1)
	Mild	493	82 (16.6)	(13.5, 20.2)	226	33 (14.6)	(10.3, 19.9)
	Moderate	493	40 (8.1)	(5.9, 10.9)	226	19 (8.4)	(5.1, 12.8)
	Severe	493	1 (0.2)	(0.0, 1.1)	226	0	(0.0, 1.6)
	Grade 4	493	0	(0.0, 0.7)	226	0	(0.0, 1.6)
	Headache[d]						
	Any	493	24 (4.9)	(3.1, 7.2)	226	11 (4.9)	(2.5, 8.5)
	Mild	493	17 (3.4)	(2.0, 5.5)	226	10 (4.4)	(2.1, 8.0)
	Moderate	493	7 (1.4)	(0.6, 2.9)	226	1 (0.4)	(0.0, 2.4)
	Severe	493	0	(0.0, 0.7)	226	0	(0.0, 1.6)
	Grade 4	493	0	(0.0, 0.7)	226	0	(0.0, 1.6)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Chills[d]						
	Any	493	17 (3.4)	(2.0, 5.5)	226	6 (2.7)	(1.0, 5.7)
	Mild	493	13 (2.6)	(1.4, 4.5)	226	6 (2.7)	(1.0, 5.7)
	Moderate	493	3 (0.6)	(0.1, 1.8)	226	0	(0.0, 1.6)
	Severe	493	1 (0.2)	(0.0, 1.1)	226	0	(0.0, 1.6)
	Grade 4	493	0	(0.0, 0.7)	226	0	(0.0, 1.6)
	Vomiting[e]						
	Any	493	8 (1.6)	(0.7, 3.2)	226	10 (4.4)	(2.1, 8.0)
	Mild	493	6 (1.2)	(0.4, 2.6)	226	9 (4.0)	(1.8, 7.4)
	Moderate	493	2 (0.4)	(0.0, 1.5)	226	1 (0.4)	(0.0, 2.4)
	Severe	493	0	(0.0, 0.7)	226	0	(0.0, 1.6)
	Grade 4	493	0	(0.0, 0.7)	226	0	(0.0, 1.6)
	Diarrhea[f]						
	Any	493	23 (4.7)	(3.0, 6.9)	226	11 (4.9)	(2.5, 8.5)
	Mild	493	17 (3.4)	(2.0, 5.5)	226	9 (4.0)	(1.8, 7.4)
	Moderate	493	6 (1.2)	(0.4, 2.6)	226	2 (0.9)	(0.1, 3.2)
	Severe	493	0	(0.0, 0.7)	226	0	(0.0, 1.6)
	Grade 4	493	0	(0.0, 0.7)	226	0	(0.0, 1.6)
	New or worsened muscle pain[d]						
	Any	493	11 (2.2)	(1.1, 4.0)	226	4 (1.8)	(0.5, 4.5)
	Mild	493	8 (1.6)	(0.7, 3.2)	226	4 (1.8)	(0.5, 4.5)
	Moderate	493	3 (0.6)	(0.1, 1.8)	226	0	(0.0, 1.6)
	Severe	493	0	(0.0, 0.7)	226	0	(0.0, 1.6)
	Grade 4	493	0	(0.0, 0.7)	226	0	(0.0, 1.6)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	New or worsened joint pain[d]						
	Any	493	7 (1.4)	(0.6, 2.9)	226	2 (0.9)	(0.1, 3.2)
	Mild	493	5 (1.0)	(0.3, 2.4)	226	2 (0.9)	(0.1, 3.2)
	Moderate	493	1 (0.2)	(0.0, 1.1)	226	0	(0.0, 1.6)
	Severe	493	1 (0.2)	(0.0, 1.1)	226	0	(0.0, 1.6)
	Grade 4	493	0	(0.0, 0.7)	226	0	(0.0, 1.6)
	Any systemic event[g]	498	157 (31.5)	(27.5, 35.8)	226	69 (30.5)	(24.6, 37.0)
	Use of antipyretic or pain medication[h]	498	40 (8.0)	(5.8, 10.8)	226	16 (7.1)	(4.1, 11.2)
Any dose	Fever						
	≥38.0°C	1597	169 (10.6)	(9.1, 12.2)	782	79 (10.1)	(8.1, 12.4)
	≥38.0°C to 38.4°C	1597	84 (5.3)	(4.2, 6.5)	782	35 (4.5)	(3.1, 6.2)
	>38.4°C to 38.9°C	1597	51 (3.2)	(2.4, 4.2)	782	29 (3.7)	(2.5, 5.3)
	>38.9°C to 40.0°C	1597	32 (2.0)	(1.4, 2.8)	782	15 (1.9)	(1.1, 3.1)
	>40.0°C	1597	2 (0.1)	(0.0, 0.5)	782	0	(0.0, 0.5)
	Fatigue[d]						
	Any	1590	732 (46.0)	(43.6, 48.5)	780	338 (43.3)	(39.8, 46.9)
	Mild	1590	409 (25.7)	(23.6, 27.9)	780	189 (24.2)	(21.3, 27.4)
	Moderate	1590	314 (19.7)	(17.8, 21.8)	780	142 (18.2)	(15.6, 21.1)
	Severe	1590	9 (0.6)	(0.3, 1.1)	780	7 (0.9)	(0.4, 1.8)
	Grade 4	1590	0	(0.0, 0.2)	780	0	(0.0, 0.5)
	Headache[d]						
	Any	1590	134 (8.4)	(7.1, 9.9)	780	66 (8.5)	(6.6, 10.6)
	Mild	1590	105 (6.6)	(5.4, 7.9)	780	49 (6.3)	(4.7, 8.2)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	1590	29 (1.8)	(1.2, 2.6)	780	16 (2.1)	(1.2, 3.3)
	Severe	1590	0	(0.0, 0.2)	780	1 (0.1)	(0.0, 0.7)
	Grade 4	1590	0	(0.0, 0.2)	780	0	(0.0, 0.5)
	Chills[d]						
	Any	1590	90 (5.7)	(4.6, 6.9)	780	40 (5.1)	(3.7, 6.9)
	Mild	1590	63 (4.0)	(3.1, 5.0)	780	33 (4.2)	(2.9, 5.9)
	Moderate	1590	24 (1.5)	(1.0, 2.2)	780	7 (0.9)	(0.4, 1.8)
	Severe	1590	3 (0.2)	(0.0, 0.6)	780	0	(0.0, 0.5)
	Grade 4	1590	0	(0.0, 0.2)	780	0	(0.0, 0.5)
	Vomiting[e]						
	Any	1590	97 (6.1)	(5.0, 7.4)	780	48 (6.2)	(4.6, 8.1)
	Mild	1590	83 (5.2)	(4.2, 6.4)	780	38 (4.9)	(3.5, 6.6)
	Moderate	1590	14 (0.9)	(0.5, 1.5)	780	10 (1.3)	(0.6, 2.3)
	Severe	1590	0	(0.0, 0.2)	780	0	(0.0, 0.5)
	Grade 4	1590	0	(0.0, 0.2)	780	0	(0.0, 0.5)
	Diarrhea[f]						
	Any	1590	214 (13.5)	(11.8, 15.2)	780	110 (14.1)	(11.7, 16.7)
	Mild	1590	190 (11.9)	(10.4, 13.6)	780	100 (12.8)	(10.6, 15.4)
	Moderate	1590	23 (1.4)	(0.9, 2.2)	780	10 (1.3)	(0.6, 2.3)
	Severe	1590	1 (0.1)	(0.0, 0.3)	780	0	(0.0, 0.5)
	Grade 4	1590	0	(0.0, 0.2)	780	0	(0.0, 0.5)
	New or worsened muscle pain[d]						
	Any	1590	85 (5.3)	(4.3, 6.6)	780	33 (4.2)	(2.9, 5.9)
	Mild	1590	61 (3.8)	(2.9, 4.9)	780	30 (3.8)	(2.6, 5.4)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	1590	23 (1.4)	(0.9, 2.2)	780	3 (0.4)	(0.1, 1.1)
	Severe	1590	1 (0.1)	(0.0, 0.3)	780	0	(0.0, 0.5)
	Grade 4	1590	0	(0.0, 0.2)	780	0	(0.0, 0.5)
	New or worsened joint pain[d]						
	Any	1590	40 (2.5)	(1.8, 3.4)	780	19 (2.4)	(1.5, 3.8)
	Mild	1590	30 (1.9)	(1.3, 2.7)	780	14 (1.8)	(1.0, 3.0)
	Moderate	1590	9 (0.6)	(0.3, 1.1)	780	5 (0.6)	(0.2, 1.5)
	Severe	1590	1 (0.1)	(0.0, 0.3)	780	0	(0.0, 0.5)
	Grade 4	1590	0	(0.0, 0.2)	780	0	(0.0, 0.5)
	Any systemic event[g]	1597	900 (56.4)	(53.9, 58.8)	782	426 (54.5)	(50.9, 58.0)
	Use of antipyretic or pain medication[b]	1597	313 (19.6)	(17.7, 21.6)	782	130 (16.6)	(14.1, 19.4)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 2 to <5 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Events and use of antipyretic or pain medication were collected in the e-diary and unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person.
Note: Participants 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.
a. N = number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants 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 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: 12MAY2022 (08:23) Source Data: adfacevd Table Generation: 13MAY2022 (07:04)
(Cutoff Date: 29APR2022, Snapshot Date: 11MAY2022) Output File: ./nda2_ubped/C4591007_6M_LT5Y_SAF_IMM_EUA_MAY2022/adce_s020_se_p2_bs_5

Table 5. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	87	9 (10.3)	(4.8, 18.7)	43	3 (7.0)	(1.5, 19.1)
	Mild	87	8 (9.2)	(4.1, 17.3)	43	3 (7.0)	(1.5, 19.1)
	Moderate	87	1 (1.1)	(0.0, 6.2)	43	0	(0.0, 8.2)
	Severe	87	0	(0.0, 4.2)	43	0	(0.0, 8.2)
	Grade 4	87	0	(0.0, 4.2)	43	0	(0.0, 8.2)
	Swelling[d]						
	Any	87	5 (5.7)	(1.9, 12.9)	43	1 (2.3)	(0.1, 12.3)
	Mild	87	5 (5.7)	(1.9, 12.9)	43	1 (2.3)	(0.1, 12.3)
	Moderate	87	0	(0.0, 4.2)	43	0	(0.0, 8.2)
	Severe	87	0	(0.0, 4.2)	43	0	(0.0, 8.2)
	Grade 4	87	0	(0.0, 4.2)	43	0	(0.0, 8.2)
	Tenderness at the injection site[e]						
	Any	87	16 (18.4)	(10.9, 28.1)	42	3 (7.1)	(1.5, 19.5)
	Mild	87	13 (14.9)	(8.2, 24.2)	42	3 (7.1)	(1.5, 19.5)
	Moderate	87	3 (3.4)	(0.7, 9.7)	42	0	(0.0, 8.4)
	Severe	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Grade 4	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Any local reaction[f]	87	22 (25.3)	(16.6, 35.7)	43	5 (11.6)	(3.9, 25.1)
2	Redness[d]						
	Any	87	6 (6.9)	(2.6, 14.4)	42	1 (2.4)	(0.1, 12.6)
	Mild	87	6 (6.9)	(2.6, 14.4)	42	1 (2.4)	(0.1, 12.6)
	Moderate	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)

Table 5. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Grade 4	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Swelling[d]						
	Any	87	3 (3.4)	(0.7, 9.7)	42	0	(0.0, 8.4)
	Mild	87	3 (3.4)	(0.7, 9.7)	42	0	(0.0, 8.4)
	Moderate	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Severe	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Grade 4	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Tenderness at the injection site[e]						
	Any	87	18 (20.7)	(12.7, 30.7)	42	1 (2.4)	(0.1, 12.6)
	Mild	87	14 (16.1)	(9.1, 25.5)	42	1 (2.4)	(0.1, 12.6)
	Moderate	87	4 (4.6)	(1.3, 11.4)	42	0	(0.0, 8.4)
	Severe	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Grade 4	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Any local reaction[f]	87	20 (23.0)	(14.6, 33.2)	42	2 (4.8)	(0.6, 16.2)
3	Redness[d]						
	Any	19	1 (5.3)	(0.1, 26.0)	6	0	(0.0, 45.9)
	Mild	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)
	Moderate	19	1 (5.3)	(0.1, 26.0)	6	0	(0.0, 45.9)
	Severe	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)
	Grade 4	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)
	Swelling[d]						
	Any	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)

Table 5. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)
	Moderate	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)
	Severe	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)
	Grade 4	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)
	Tenderness at the injection site[e]						
	Any	19	2 (10.5)	(1.3, 33.1)	6	1 (16.7)	(0.4, 64.1)
	Mild	19	1 (5.3)	(0.1, 26.0)	6	1 (16.7)	(0.4, 64.1)
	Moderate	19	1 (5.3)	(0.1, 26.0)	6	0	(0.0, 45.9)
	Severe	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)
	Grade 4	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)
	Any local reaction[f]	19	3 (15.8)	(3.4, 39.6)	6	1 (16.7)	(0.4, 64.1)
Any dose	Redness[d]						
	Any	88	12 (13.6)	(7.2, 22.6)	43	3 (7.0)	(1.5, 19.1)
	Mild	88	10 (11.4)	(5.6, 19.9)	43	3 (7.0)	(1.5, 19.1)
	Moderate	88	2 (2.3)	(0.3, 8.0)	43	0	(0.0, 8.2)
	Severe	88	0	(0.0, 4.1)	43	0	(0.0, 8.2)
	Grade 4	88	0	(0.0, 4.1)	43	0	(0.0, 8.2)
	Swelling[d]						
	Any	88	6 (6.8)	(2.5, 14.3)	43	1 (2.3)	(0.1, 12.3)
	Mild	88	6 (6.8)	(2.5, 14.3)	43	1 (2.3)	(0.1, 12.3)
	Moderate	88	0	(0.0, 4.1)	43	0	(0.0, 8.2)
	Severe	88	0	(0.0, 4.1)	43	0	(0.0, 8.2)
	Grade 4	88	0	(0.0, 4.1)	43	0	(0.0, 8.2)

Table 5. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Tenderness at the injection site[e]						
	Any	88	25 (28.4)	(19.3, 39.0)	42	4 (9.5)	(2.7, 22.6)
	Mild	88	18 (20.5)	(12.6, 30.4)	42	4 (9.5)	(2.7, 22.6)
	Moderate	88	7 (8.0)	(3.3, 15.7)	42	0	(0.0, 8.4)
	Severe	88	0	(0.0, 4.1)	42	0	(0.0, 8.4)
	Grade 4	88	0	(0.0, 4.1)	42	0	(0.0, 8.4)
	Any local reaction[f]	88	31 (35.2)	(25.3, 46.1)	43	6 (14.0)	(5.3, 27.9)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Reactions were collected in the e-diary and unscheduled clinical assessments from Day 1 through Day 7 after each vaccination.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
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.
a. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: ≥0.5 to 2.0 cm; moderate: >2.0 to 7.0 cm; severe: >7.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: hurts if gently touched; moderate: hurts if gently touched with crying; severe: causes limitation of limb movement; Grade 4: emergency room visit or hospitalization for severe tenderness at the injection site.
f. Any local reaction: any redness ≥0.5 cm, any swelling ≥0.5 cm, or any tenderness at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 12MAY2022 (06:32) Source Data: adfacevd Table Generation: 12MAY2022 (22:47)
(Cutoff Date: 29APR2022, Snapshot Date: 11MAY2022) Output File: ./nda2_ubped/C4591007_6M_LT5Y_SAF_IMM_EUA_MAY2022/adce_s10_lr_p2_bs_2

Table 6. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Redness[d]						
	Any	1075	113 (10.5)	(8.7, 12.5)	539	41 (7.6)	(5.5, 10.2)
	Mild	1075	104 (9.7)	(8.0, 11.6)	539	38 (7.1)	(5.0, 9.5)
	Moderate	1075	9 (0.8)	(0.4, 1.6)	539	3 (0.6)	(0.1, 1.6)
	Severe	1075	0	(0.0, 0.3)	539	0	(0.0, 0.7)
	Grade 4	1075	0	(0.0, 0.3)	539	0	(0.0, 0.7)
	Swelling[d]						
	Any	1075	41 (3.8)	(2.8, 5.1)	539	14 (2.6)	(1.4, 4.3)
	Mild	1075	35 (3.3)	(2.3, 4.5)	539	12 (2.2)	(1.2, 3.9)
	Moderate	1075	6 (0.6)	(0.2, 1.2)	539	2 (0.4)	(0.0, 1.3)
	Severe	1075	0	(0.0, 0.3)	539	0	(0.0, 0.7)
	Grade 4	1075	0	(0.0, 0.3)	539	0	(0.0, 0.7)
	Tenderness at the injection site[e]						
	Any	1061	174 (16.4)	(14.2, 18.8)	536	61 (11.4)	(8.8, 14.4)
	Mild	1061	166 (15.6)	(13.5, 18.0)	536	56 (10.4)	(8.0, 13.4)
	Moderate	1061	8 (0.8)	(0.3, 1.5)	536	5 (0.9)	(0.3, 2.2)
	Severe	1061	0	(0.0, 0.3)	536	0	(0.0, 0.7)
	Grade 4	1061	0	(0.0, 0.3)	536	0	(0.0, 0.7)
	Any local reaction[f]	1075	254 (23.6)	(21.1, 26.3)	539	97 (18.0)	(14.8, 21.5)
2	Redness[d]						
	Any	1049	100 (9.5)	(7.8, 11.5)	536	38 (7.1)	(5.1, 9.6)
	Mild	1049	91 (8.7)	(7.0, 10.5)	536	35 (6.5)	(4.6, 9.0)
	Moderate	1049	9 (0.9)	(0.4, 1.6)	536	3 (0.6)	(0.1, 1.6)

Table 6. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Severe	1049	0	(0.0, 0.4)	536	0	(0.0, 0.7)
	Grade 4	1049	0	(0.0, 0.4)	536	0	(0.0, 0.7)
	Swelling[d]						
	Any	1049	42 (4.0)	(2.9, 5.4)	536	9 (1.7)	(0.8, 3.2)
	Mild	1049	36 (3.4)	(2.4, 4.7)	536	8 (1.5)	(0.6, 2.9)
	Moderate	1049	6 (0.6)	(0.2, 1.2)	536	1 (0.2)	(0.0, 1.0)
	Severe	1049	0	(0.0, 0.4)	536	0	(0.0, 0.7)
	Grade 4	1049	0	(0.0, 0.4)	536	0	(0.0, 0.7)
	Tenderness at the injection site[e]						
	Any	1039	152 (14.6)	(12.5, 16.9)	535	48 (9.0)	(6.7, 11.7)
	Mild	1039	139 (13.4)	(11.4, 15.6)	535	40 (7.5)	(5.4, 10.0)
	Moderate	1039	12 (1.2)	(0.6, 2.0)	535	8 (1.5)	(0.6, 2.9)
	Severe	1039	1 (0.1)	(0.0, 0.5)	535	0	(0.0, 0.7)
	Grade 4	1039	0	(0.0, 0.4)	535	0	(0.0, 0.7)
	Any local reaction[f]	1049	227 (21.6)	(19.2, 24.3)	536	76 (14.2)	(11.3, 17.4)
3	Redness[d]						
	Any	342	24 (7.0)	(4.5, 10.3)	161	9 (5.6)	(2.6, 10.3)
	Mild	342	17 (5.0)	(2.9, 7.8)	161	8 (5.0)	(2.2, 9.6)
	Moderate	342	6 (1.8)	(0.6, 3.8)	161	1 (0.6)	(0.0, 3.4)
	Severe	342	1 (0.3)	(0.0, 1.6)	161	0	(0.0, 2.3)
	Grade 4	342	0	(0.0, 1.1)	161	0	(0.0, 2.3)
	Swelling[d]						
	Any	342	10 (2.9)	(1.4, 5.3)	161	3 (1.9)	(0.4, 5.3)

Table 6. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Mild	342	7 (2.0)	(0.8, 4.2)	161	3 (1.9)	(0.4, 5.3)
	Moderate	342	3 (0.9)	(0.2, 2.5)	161	0	(0.0, 2.3)
	Severe	342	0	(0.0, 1.1)	161	0	(0.0, 2.3)
	Grade 4	342	0	(0.0, 1.1)	161	0	(0.0, 2.3)
	Tenderness at the injection site[e]						
	Any	339	56 (16.5)	(12.7, 20.9)	161	19 (11.8)	(7.3, 17.8)
	Mild	339	50 (14.7)	(11.1, 19.0)	161	16 (9.9)	(5.8, 15.6)
	Moderate	339	6 (1.8)	(0.7, 3.8)	161	3 (1.9)	(0.4, 5.3)
	Severe	339	0	(0.0, 1.1)	161	0	(0.0, 2.3)
	Grade 4	339	0	(0.0, 1.1)	161	0	(0.0, 2.3)
	Any local reaction[f]	342	71 (20.8)	(16.6, 25.5)	161	25 (15.5)	(10.3, 22.1)
Any dose	Redness[d]						
	Any	1078	194 (18.0)	(15.7, 20.4)	541	73 (13.5)	(10.7, 16.7)
	Mild	1078	170 (15.8)	(13.6, 18.1)	541	66 (12.2)	(9.6, 15.3)
	Moderate	1078	23 (2.1)	(1.4, 3.2)	541	7 (1.3)	(0.5, 2.6)
	Severe	1078	1 (0.1)	(0.0, 0.5)	541	0	(0.0, 0.7)
	Grade 4	1078	0	(0.0, 0.3)	541	0	(0.0, 0.7)
	Swelling[d]						
	Any	1078	80 (7.4)	(5.9, 9.2)	541	22 (4.1)	(2.6, 6.1)
	Mild	1078	66 (6.1)	(4.8, 7.7)	541	19 (3.5)	(2.1, 5.4)
	Moderate	1078	14 (1.3)	(0.7, 2.2)	541	3 (0.6)	(0.1, 1.6)
	Severe	1078	0	(0.0, 0.3)	541	0	(0.0, 0.7)
	Grade 4	1078	0	(0.0, 0.3)	541	0	(0.0, 0.7)

Table 6. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Tenderness at the injection site[e]						
	Any	1070	281 (26.3)	(23.6, 29.0)	540	104 (19.3)	(16.0, 22.8)
	Mild	1070	255 (23.8)	(21.3, 26.5)	540	90 (16.7)	(13.6, 20.1)
	Moderate	1070	25 (2.3)	(1.5, 3.4)	540	14 (2.6)	(1.4, 4.3)
	Severe	1070	1 (0.1)	(0.0, 0.5)	540	0	(0.0, 0.7)
	Grade 4	1070	0	(0.0, 0.3)	540	0	(0.0, 0.7)
	Any local reaction[f]	1078	398 (36.9)	(34.0, 39.9)	541	152 (28.1)	(24.3, 32.1)

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Reactions were collected in the e-diary and unscheduled clinical assessments from Day 1 through Day 7 after each vaccination.
Note: Grade 4 reactions were classified by the investigator or medically qualified person.
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.
a. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: ≥0.5 to 2.0 cm; moderate: >2.0 to 7.0 cm; severe: >7.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).
e. Mild: hurts if gently touched; moderate: hurts if gently touched with crying; severe: causes limitation of limb movement; Grade 4: emergency room visit or hospitalization for severe tenderness at the injection site.
f. Any local reaction: any redness ≥0.5 cm, any swelling ≥0.5 cm, or any tenderness at the injection site.
PFIZER CONFIDENTIAL SDTM Creation: 12MAY2022 (06:32) Source Data: adfacevd Table Generation: 12MAY2022 (22:47)
(Cutoff Date: 29APR2022, Snapshot Date: 11MAY2022) Output File: ./nda2_ubped/C4591007_6M_LT5Y_SAF_IMM_EUA_MAY2022/adce_s10_lr_p2_bs_2

Table 7. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	≥38.0°C	87	8 (9.2)	(4.1, 17.3)	43	5 (11.6)	(3.9, 25.1)
	≥38.0°C to 38.4°C	87	3 (3.4)	(0.7, 9.7)	43	1 (2.3)	(0.1, 12.3)
	>38.4°C to 38.9°C	87	3 (3.4)	(0.7, 9.7)	43	3 (7.0)	(1.5, 19.1)
	>38.9°C to 40.0°C	87	2 (2.3)	(0.3, 8.1)	43	1 (2.3)	(0.1, 12.3)
	>40.0°C	87	0	(0.0, 4.2)	43	0	(0.0, 8.2)
	Decreased appetite[d]						
	Any	87	26 (29.9)	(20.5, 40.6)	42	11 (26.2)	(13.9, 42.0)
	Mild	87	13 (14.9)	(8.2, 24.2)	42	3 (7.1)	(1.5, 19.5)
	Moderate	87	12 (13.8)	(7.3, 22.9)	42	8 (19.0)	(8.6, 34.1)
	Severe	87	1 (1.1)	(0.0, 6.2)	42	0	(0.0, 8.4)
	Grade 4	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Drowsiness[e]						
	Any	87	27 (31.0)	(21.5, 41.9)	42	13 (31.0)	(17.6, 47.1)
	Mild	87	22 (25.3)	(16.6, 35.7)	42	7 (16.7)	(7.0, 31.4)
	Moderate	87	5 (5.7)	(1.9, 12.9)	42	6 (14.3)	(5.4, 28.5)
	Severe	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Grade 4	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Irritability[f]						
	Any	87	46 (52.9)	(41.9, 63.7)	42	16 (38.1)	(23.6, 54.4)
	Mild	87	24 (27.6)	(18.5, 38.2)	42	4 (9.5)	(2.7, 22.6)
	Moderate	87	22 (25.3)	(16.6, 35.7)	42	12 (28.6)	(15.7, 44.6)
	Severe	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Grade 4	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)

Table 7. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any systemic event[g]	87	60 (69.0)	(58.1, 78.5)	43	23 (53.5)	(37.7, 68.8)
	Use of antipyretic or pain medication[h]	87	24 (27.6)	(18.5, 38.2)	43	10 (23.3)	(11.8, 38.6)
2	Fever						
	≥38.0°C	87	4 (4.6)	(1.3, 11.4)	42	0	(0.0, 8.4)
	≥38.0°C to 38.4°C	87	2 (2.3)	(0.3, 8.1)	42	0	(0.0, 8.4)
	>38.4°C to 38.9°C	87	1 (1.1)	(0.0, 6.2)	42	0	(0.0, 8.4)
	>38.9°C to 40.0°C	87	1 (1.1)	(0.0, 6.2)	42	0	(0.0, 8.4)
	>40.0°C	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Decreased appetite[d]						
	Any	87	21 (24.1)	(15.6, 34.5)	42	6 (14.3)	(5.4, 28.5)
	Mild	87	11 (12.6)	(6.5, 21.5)	42	2 (4.8)	(0.6, 16.2)
	Moderate	87	8 (9.2)	(4.1, 17.3)	42	4 (9.5)	(2.7, 22.6)
	Severe	87	2 (2.3)	(0.3, 8.1)	42	0	(0.0, 8.4)
	Grade 4	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Drowsiness[e]						
	Any	87	21 (24.1)	(15.6, 34.5)	42	5 (11.9)	(4.0, 25.6)
	Mild	87	15 (17.2)	(10.0, 26.8)	42	3 (7.1)	(1.5, 19.5)
	Moderate	87	5 (5.7)	(1.9, 12.9)	42	2 (4.8)	(0.6, 16.2)
	Severe	87	1 (1.1)	(0.0, 6.2)	42	0	(0.0, 8.4)
	Grade 4	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Irritability[f]						
	Any	87	38 (43.7)	(33.1, 54.7)	42	9 (21.4)	(10.3, 36.8)
	Mild	87	17 (19.5)	(11.8, 29.4)	42	2 (4.8)	(0.6, 16.2)

Table 7. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	87	21 (24.1)	(15.6, 34.5)	42	7 (16.7)	(7.0, 31.4)
	Severe	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Grade 4	87	0	(0.0, 4.2)	42	0	(0.0, 8.4)
	Any systemic event[g]	87	45 (51.7)	(40.8, 62.6)	42	14 (33.3)	(19.6, 49.5)
	Use of antipyretic or pain medication[h]	87	13 (14.9)	(8.2, 24.2)	42	4 (9.5)	(2.7, 22.6)
3	Fever						
	≥38.0°C	19	2 (10.5)	(1.3, 33.1)	6	0	(0.0, 45.9)
	≥38.0°C to 38.4°C	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)
	>38.4°C to 38.9°C	19	1 (5.3)	(0.1, 26.0)	6	0	(0.0, 45.9)
	>38.9°C to 40.0°C	19	1 (5.3)	(0.1, 26.0)	6	0	(0.0, 45.9)
	>40.0°C	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)
	Decreased appetite[d]						
	Any	19	5 (26.3)	(9.1, 51.2)	6	0	(0.0, 45.9)
	Mild	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)
	Moderate	19	4 (21.1)	(6.1, 45.6)	6	0	(0.0, 45.9)
	Severe	19	1 (5.3)	(0.1, 26.0)	6	0	(0.0, 45.9)
	Grade 4	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)
	Drowsiness[e]						
	Any	19	7 (36.8)	(16.3, 61.6)	6	0	(0.0, 45.9)
	Mild	19	4 (21.1)	(6.1, 45.6)	6	0	(0.0, 45.9)
	Moderate	19	3 (15.8)	(3.4, 39.6)	6	0	(0.0, 45.9)
	Severe	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)
	Grade 4	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)

Table 7. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Irritability[f]						
	Any	19	9 (47.4)	(24.4, 71.1)	6	1 (16.7)	(0.4, 64.1)
	Mild	19	2 (10.5)	(1.3, 33.1)	6	0	(0.0, 45.9)
	Moderate	19	7 (36.8)	(16.3, 61.6)	6	1 (16.7)	(0.4, 64.1)
	Severe	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)
	Grade 4	19	0	(0.0, 17.6)	6	0	(0.0, 45.9)
	Any systemic event[g]	19	10 (52.6)	(28.9, 75.6)	6	1 (16.7)	(0.4, 64.1)
	Use of antipyretic or pain medication[h]	19	5 (26.3)	(9.1, 51.2)	6	1 (16.7)	(0.4, 64.1)
Any dose	Fever						
	≥38.0°C	88	13 (14.8)	(8.1, 23.9)	43	5 (11.6)	(3.9, 25.1)
	≥38.0°C to 38.4°C	88	4 (4.5)	(1.3, 11.2)	43	1 (2.3)	(0.1, 12.3)
	>38.4°C to 38.9°C	88	5 (5.7)	(1.9, 12.8)	43	3 (7.0)	(1.5, 19.1)
	>38.9°C to 40.0°C	88	4 (4.5)	(1.3, 11.2)	43	1 (2.3)	(0.1, 12.3)
	>40.0°C	88	0	(0.0, 4.1)	43	0	(0.0, 8.2)
	Decreased appetite[d]						
	Any	88	41 (46.6)	(35.9, 57.5)	42	15 (35.7)	(21.6, 52.0)
	Mild	88	16 (18.2)	(10.8, 27.8)	42	5 (11.9)	(4.0, 25.6)
	Moderate	88	21 (23.9)	(15.4, 34.1)	42	10 (23.8)	(12.1, 39.5)
	Severe	88	4 (4.5)	(1.3, 11.2)	42	0	(0.0, 8.4)
	Grade 4	88	0	(0.0, 4.1)	42	0	(0.0, 8.4)
	Drowsiness[e]						
	Any	88	42 (47.7)	(37.0, 58.6)	42	14 (33.3)	(19.6, 49.5)
	Mild	88	30 (34.1)	(24.3, 45.0)	42	7 (16.7)	(7.0, 31.4)

Table 7. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	88	11 (12.5)	(6.4, 21.3)	42	7 (16.7)	(7.0, 31.4)
	Severe	88	1 (1.1)	(0.0, 6.2)	42	0	(0.0, 8.4)
	Grade 4	88	0	(0.0, 4.1)	42	0	(0.0, 8.4)
	Irritability[f]						
	Any	88	56 (63.6)	(52.7, 73.6)	42	22 (52.4)	(36.4, 68.0)
	Mild	88	19 (21.6)	(13.5, 31.6)	42	5 (11.9)	(4.0, 25.6)
	Moderate	88	37 (42.0)	(31.6, 53.0)	42	17 (40.5)	(25.6, 56.7)
	Severe	88	0	(0.0, 4.1)	42	0	(0.0, 8.4)
	Grade 4	88	0	(0.0, 4.1)	42	0	(0.0, 8.4)
	Any systemic event[g]	88	69 (78.4)	(68.4, 86.5)	43	30 (69.8)	(53.9, 82.8)
	Use of antipyretic or pain medication[h]	88	34 (38.6)	(28.4, 49.6)	43	13 (30.2)	(17.2, 46.1)

Table 7. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Positive

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Events and use of antipyretic or pain medication were collected in the e-diary and unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person.
Note: Participants 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.
a. N = number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: decreased interest in eating; moderate: decreased oral intake; severe: refusal to feed; Grade 4: emergency room visit or hospitalization for severe decreased appetite (loss of appetite).
e. Mild: increased or prolonged sleeping bouts; moderate: slightly subdued interfering with daily activity; severe: disabling; not interested in usual daily activity; Grade 4: emergency room visit or hospitalization for severe drowsiness (increased sleep).
f. Mild: easily consolable; moderate: requiring increased attention; severe: inconsolable; crying cannot be comforted; Grade 4: emergency room visit or hospitalization for severe irritability (fussiness).
g. Any systemic event: any fever ≥38.0°C, any decreased appetite, any drowsiness, or any irritability.
h. Severity was not collected for use of antipyretic or pain medication.
PFIZER CONFIDENTIAL SDTM Creation: 12MAY2022 (08:23) Source Data: adfacevd Table Generation: 13MAY2022 (07:04)
(Cutoff Date: 29APR2022, Snapshot Date: 11MAY2022) Output File: ./nda2_ubped/C4591007_6M_LT5Y_SAF_IMM_EUA_MAY2022/adce_s020_se_p2_bs_2

Table 8. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
1	Fever						
	≥38.0°C	1075	76 (7.1)	(5.6, 8.8)	539	37 (6.9)	(4.9, 9.3)
	≥38.0°C to 38.4°C	1075	38 (3.5)	(2.5, 4.8)	539	21 (3.9)	(2.4, 5.9)
	>38.4°C to 38.9°C	1075	20 (1.9)	(1.1, 2.9)	539	10 (1.9)	(0.9, 3.4)
	>38.9°C to 40.0°C	1075	17 (1.6)	(0.9, 2.5)	539	5 (0.9)	(0.3, 2.2)
	>40.0°C	1075	1 (0.1)	(0.0, 0.5)	539	1 (0.2)	(0.0, 1.0)
	Decreased appetite[d]						
	Any	1061	229 (21.6)	(19.1, 24.2)	536	112 (20.9)	(17.5, 24.6)
	Mild	1061	124 (11.7)	(9.8, 13.8)	536	70 (13.1)	(10.3, 16.2)
	Moderate	1061	103 (9.7)	(8.0, 11.6)	536	41 (7.6)	(5.5, 10.2)
	Severe	1061	2 (0.2)	(0.0, 0.7)	536	1 (0.2)	(0.0, 1.0)
	Grade 4	1061	0	(0.0, 0.3)	536	0	(0.0, 0.7)
	Drowsiness[e]						
	Any	1061	283 (26.7)	(24.0, 29.4)	536	156 (29.1)	(25.3, 33.2)
	Mild	1061	226 (21.3)	(18.9, 23.9)	536	119 (22.2)	(18.8, 26.0)
	Moderate	1061	55 (5.2)	(3.9, 6.7)	536	35 (6.5)	(4.6, 9.0)
	Severe	1061	2 (0.2)	(0.0, 0.7)	536	2 (0.4)	(0.0, 1.3)
	Grade 4	1061	0	(0.0, 0.3)	536	0	(0.0, 0.7)
	Irritability[f]						
	Any	1061	539 (50.8)	(47.7, 53.9)	536	256 (47.8)	(43.5, 52.1)
	Mild	1061	217 (20.5)	(18.1, 23.0)	536	99 (18.5)	(15.3, 22.0)
	Moderate	1061	315 (29.7)	(27.0, 32.5)	536	157 (29.3)	(25.5, 33.3)
	Severe	1061	7 (0.7)	(0.3, 1.4)	536	0	(0.0, 0.7)
	Grade 4	1061	0	(0.0, 0.3)	536	0	(0.0, 0.7)

Table 8. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Any systemic event[g]	1075	646 (60.1)	(57.1, 63.0)	539	316 (58.6)	(54.3, 62.8)
	Use of antipyretic or pain medication[h]	1075	254 (23.6)	(21.1, 26.3)	539	105 (19.5)	(16.2, 23.1)
2	Fever						
	≥38.0°C	1049	78 (7.4)	(5.9, 9.2)	536	35 (6.5)	(4.6, 9.0)
	≥38.0°C to 38.4°C	1049	36 (3.4)	(2.4, 4.7)	536	17 (3.2)	(1.9, 5.0)
	>38.4°C to 38.9°C	1049	19 (1.8)	(1.1, 2.8)	536	11 (2.1)	(1.0, 3.6)
	>38.9°C to 40.0°C	1049	22 (2.1)	(1.3, 3.2)	536	7 (1.3)	(0.5, 2.7)
	>40.0°C	1049	1 (0.1)	(0.0, 0.5)	536	0	(0.0, 0.7)
	Decreased appetite[d]						
	Any	1039	230 (22.1)	(19.6, 24.8)	535	97 (18.1)	(15.0, 21.7)
	Mild	1039	146 (14.1)	(12.0, 16.3)	535	58 (10.8)	(8.3, 13.8)
	Moderate	1039	82 (7.9)	(6.3, 9.7)	535	38 (7.1)	(5.1, 9.6)
	Severe	1039	2 (0.2)	(0.0, 0.7)	535	1 (0.2)	(0.0, 1.0)
	Grade 4	1039	0	(0.0, 0.4)	535	0	(0.0, 0.7)
	Drowsiness[e]						
	Any	1039	249 (24.0)	(21.4, 26.7)	535	118 (22.1)	(18.6, 25.8)
	Mild	1039	185 (17.8)	(15.5, 20.3)	535	93 (17.4)	(14.3, 20.9)
	Moderate	1039	61 (5.9)	(4.5, 7.5)	535	24 (4.5)	(2.9, 6.6)
	Severe	1039	3 (0.3)	(0.1, 0.8)	535	1 (0.2)	(0.0, 1.0)
	Grade 4	1039	0	(0.0, 0.4)	535	0	(0.0, 0.7)
	Irritability[f]						
	Any	1039	497 (47.8)	(44.8, 50.9)	535	227 (42.4)	(38.2, 46.7)
	Mild	1039	194 (18.7)	(16.3, 21.2)	535	83 (15.5)	(12.6, 18.9)

Table 8. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	1039	296 (28.5)	(25.8, 31.3)	535	139 (26.0)	(22.3, 29.9)
	Severe	1039	7 (0.7)	(0.3, 1.4)	535	5 (0.9)	(0.3, 2.2)
	Grade 4	1039	0	(0.0, 0.4)	535	0	(0.0, 0.7)
	Any systemic event[g]	1049	590 (56.2)	(53.2, 59.3)	536	278 (51.9)	(47.5, 56.2)
	Use of antipyretic or pain medication[h]	1049	229 (21.8)	(19.4, 24.5)	536	106 (19.8)	(16.5, 23.4)
3	Fever						
	≥38.0°C	342	23 (6.7)	(4.3, 9.9)	161	10 (6.2)	(3.0, 11.1)
	≥38.0°C to 38.4°C	342	14 (4.1)	(2.3, 6.8)	161	7 (4.3)	(1.8, 8.8)
	>38.4°C to 38.9°C	342	4 (1.2)	(0.3, 3.0)	161	2 (1.2)	(0.2, 4.4)
	>38.9°C to 40.0°C	342	4 (1.2)	(0.3, 3.0)	161	1 (0.6)	(0.0, 3.4)
	>40.0°C	342	1 (0.3)	(0.0, 1.6)	161	0	(0.0, 2.3)
	Decreased appetite[d]						
	Any	339	67 (19.8)	(15.7, 24.4)	161	23 (14.3)	(9.3, 20.7)
	Mild	339	41 (12.1)	(8.8, 16.0)	161	13 (8.1)	(4.4, 13.4)
	Moderate	339	23 (6.8)	(4.3, 10.0)	161	10 (6.2)	(3.0, 11.1)
	Severe	339	3 (0.9)	(0.2, 2.6)	161	0	(0.0, 2.3)
	Grade 4	339	0	(0.0, 1.1)	161	0	(0.0, 2.3)
	Drowsiness[e]						
	Any	339	65 (19.2)	(15.1, 23.8)	161	22 (13.7)	(8.8, 20.0)
	Mild	339	46 (13.6)	(10.1, 17.7)	161	15 (9.3)	(5.3, 14.9)
	Moderate	339	18 (5.3)	(3.2, 8.3)	161	6 (3.7)	(1.4, 7.9)
	Severe	339	1 (0.3)	(0.0, 1.6)	161	1 (0.6)	(0.0, 3.4)
	Grade 4	339	0	(0.0, 1.1)	161	0	(0.0, 2.3)

Table 8. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Irritability[f]						
	Any	339	148 (43.7)	(38.3, 49.1)	161	63 (39.1)	(31.5, 47.1)
	Mild	339	54 (15.9)	(12.2, 20.3)	161	27 (16.8)	(11.4, 23.5)
	Moderate	339	93 (27.4)	(22.8, 32.5)	161	36 (22.4)	(16.2, 29.6)
	Severe	339	1 (0.3)	(0.0, 1.6)	161	0	(0.0, 2.3)
	Grade 4	339	0	(0.0, 1.1)	161	0	(0.0, 2.3)
	Any systemic event[g]	342	177 (51.8)	(46.3, 57.2)	161	76 (47.2)	(39.3, 55.2)
	Use of antipyretic or pain medication[h]	342	64 (18.7)	(14.7, 23.3)	161	27 (16.8)	(11.4, 23.5)
Any dose	Fever						
	≥38.0°C	1078	153 (14.2)	(12.2, 16.4)	541	72 (13.3)	(10.6, 16.5)
	≥38.0°C to 38.4°C	1078	72 (6.7)	(5.3, 8.3)	541	38 (7.0)	(5.0, 9.5)
	>38.4°C to 38.9°C	1078	38 (3.5)	(2.5, 4.8)	541	20 (3.7)	(2.3, 5.7)
	>38.9°C to 40.0°C	1078	40 (3.7)	(2.7, 5.0)	541	13 (2.4)	(1.3, 4.1)
	>40.0°C	1078	3 (0.3)	(0.1, 0.8)	541	1 (0.2)	(0.0, 1.0)
	Decreased appetite[d]						
	Any	1070	406 (37.9)	(35.0, 40.9)	540	192 (35.6)	(31.5, 39.8)
	Mild	1070	209 (19.5)	(17.2, 22.0)	540	112 (20.7)	(17.4, 24.4)
	Moderate	1070	190 (17.8)	(15.5, 20.2)	540	78 (14.4)	(11.6, 17.7)
	Severe	1070	7 (0.7)	(0.3, 1.3)	540	2 (0.4)	(0.0, 1.3)
	Grade 4	1070	0	(0.0, 0.3)	540	0	(0.0, 0.7)
	Drowsiness[e]						
	Any	1070	438 (40.9)	(38.0, 43.9)	540	223 (41.3)	(37.1, 45.6)
	Mild	1070	316 (29.5)	(26.8, 32.4)	540	164 (30.4)	(26.5, 34.4)

Table 8. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
	Moderate	1070	116 (10.8)	(9.0, 12.9)	540	55 (10.2)	(7.8, 13.1)
	Severe	1070	6 (0.6)	(0.2, 1.2)	540	4 (0.7)	(0.2, 1.9)
	Grade 4	1070	0	(0.0, 0.3)	540	0	(0.0, 0.7)
	Irritability[f]						
	Any	1070	734 (68.6)	(65.7, 71.4)	540	344 (63.7)	(59.5, 67.8)
	Mild	1070	216 (20.2)	(17.8, 22.7)	540	97 (18.0)	(14.8, 21.5)
	Moderate	1070	503 (47.0)	(44.0, 50.1)	540	242 (44.8)	(40.6, 49.1)
	Severe	1070	15 (1.4)	(0.8, 2.3)	540	5 (0.9)	(0.3, 2.1)
	Grade 4	1070	0	(0.0, 0.3)	540	0	(0.0, 0.7)
	Any systemic event[g]	1078	827 (76.7)	(74.1, 79.2)	541	396 (73.2)	(69.3, 76.9)
	Use of antipyretic or pain medication[h]	1078	418 (38.8)	(35.9, 41.8)	541	186 (34.4)	(30.4, 38.6)

Table 8. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status – Phase 2/3 – Blinded Placebo-Controlled Follow-Up Period – 6 Months to <2 Years of Age – Safety Population Baseline SARS-CoV-2 Status: Negative

		Vaccine Group (as Administered)					
		BNT162b2 (3 µg)			Placebo		
Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Abbreviations: NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein–binding; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Events and use of antipyretic or pain medication were collected in the e-diary and unscheduled clinical assessments from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person.
Note: Participants 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.
a. N = number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified characteristic.
c. Exact 2-sided CI based on the Clopper and Pearson method.
d. Mild: decreased interest in eating; moderate: decreased oral intake; severe: refusal to feed; Grade 4: emergency room visit or hospitalization for severe decreased appetite (loss of appetite).
e. Mild: increased or prolonged sleeping bouts; moderate: slightly subdued interfering with daily activity; severe: disabling; not interested in usual daily activity; Grade 4: emergency room visit or hospitalization for severe drowsiness (increased sleep).
f. Mild: easily consolable; moderate: requiring increased attention; severe: inconsolable; crying cannot be comforted; Grade 4: emergency room visit or hospitalization for severe irritability (fussiness).
g. Any systemic event: any fever ≥38.0°C, any decreased appetite, any drowsiness, or any irritability.
h. Severity was not collected for use of antipyretic or pain medication.
PFIZER CONFIDENTIAL SDTM Creation: 12MAY2022 (08:23) Source Data: adfacevd Table Generation: 13MAY2022 (07:04)
(Cutoff Date: 29APR2022, Snapshot Date: 11MAY2022) Output File: ./nda2_ubped/C4591007_6M_LT5Y_SAF_IMM_EUA_MAY2022/adce_s020_se_p2_bs_2

Table 9. Local Reactions, by Maximum Severity, Within 7 Days After First Study Vaccination, by Baseline SARS-CoV-2 Status - Cohort 2 - Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 OMI (30 µg)			BNT162b2 (30 µg)		
Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Redness[d]						
Any	50	4 (8.0)	(2.2, 19.2)	45	1 (2.2)	(0.1, 11.8)
Mild	50	1 (2.0)	(0.1, 10.6)	45	1 (2.2)	(0.1, 11.8)
Moderate	50	3 (6.0)	(1.3, 16.5)	45	0	(0.0, 7.9)
Severe	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
Grade 4	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
Swelling[d]						
Any	50	5 (10.0)	(3.3, 21.8)	45	1 (2.2)	(0.1, 11.8)
Mild	50	2 (4.0)	(0.5, 13.7)	45	1 (2.2)	(0.1, 11.8)
Moderate	50	3 (6.0)	(1.3, 16.5)	45	0	(0.0, 7.9)
Severe	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
Grade 4	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
Pain at the injection site[e]						
Any	50	39 (78.0)	(64.0, 88.5)	45	29 (64.4)	(48.8, 78.1)
Mild	50	29 (58.0)	(43.2, 71.8)	45	19 (42.2)	(27.7, 57.8)
Moderate	50	10 (20.0)	(10.0, 33.7)	45	10 (22.2)	(11.2, 37.1)
Severe	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
Grade 4	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
Any local reaction[f]	50	39 (78.0)	(64.0, 88.5)	45	29 (64.4)	(48.8, 78.1)

Table 9. Local Reactions, by Maximum Severity, Within 7 Days After First Study Vaccination, by Baseline SARS-CoV-2 Status - Cohort 2 - Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 OMI (30 µg)			BNT162b2 (30 µg)		
Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Abbreviation: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Reactions were collected in the e-diary from Day 1 through Day 7 after the first study vaccination.
Note: Grade 4 reactions were classified by the investigator or a medically qualified person.
Note: Positive = positive N-binding antibody result at baseline, positive NAAT result at baseline, or medical history of COVID-19. Negative = negative N-binding antibody result at baseline, negative NAAT result at baseline, and no medical history of COVID-19.
a. N = number of participants reporting at least 1 yes or no response for the specified reaction after the first study vaccination.
b. n = Number of participants 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: 08APR2022 (22:11) Source Data: adfacevd Table Generation: 19MAY2022 (01:38)
(Data Cutoff Date: 11MAR2022, Database Snapshot Date: 8APR2022) Output File: ./nda2_ubd/C4591031_D/adce_s010_lr_bas

Table 10. Local Reactions, by Maximum Severity, Within 7 Days After First Study Vaccination, by Baseline SARS-CoV-2 Status - Cohort 2 - Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 OMI (30 µg)			BNT162b2 (30 µg)		
Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Redness[d]						
Any	244	17 (7.0)	(4.1, 10.9)	261	12 (4.6)	(2.4, 7.9)
Mild	244	12 (4.9)	(2.6, 8.4)	261	11 (4.2)	(2.1, 7.4)
Moderate	244	5 (2.0)	(0.7, 4.7)	261	1 (0.4)	(0.0, 2.1)
Severe	244	0	(0.0, 1.5)	261	0	(0.0, 1.4)
Grade 4	244	0	(0.0, 1.5)	261	0	(0.0, 1.4)
Swelling[d]						
Any	244	20 (8.2)	(5.1, 12.4)	261	26 (10.0)	(6.6, 14.3)
Mild	244	14 (5.7)	(3.2, 9.4)	261	20 (7.7)	(4.7, 11.6)
Moderate	244	6 (2.5)	(0.9, 5.3)	261	6 (2.3)	(0.8, 4.9)
Severe	244	0	(0.0, 1.5)	261	0	(0.0, 1.4)
Grade 4	244	0	(0.0, 1.5)	261	0	(0.0, 1.4)
Pain at the injection site[e]						
Any	244	190 (77.9)	(72.1, 82.9)	261	211 (80.8)	(75.5, 85.4)
Mild	244	144 (59.0)	(52.6, 65.2)	261	168 (64.4)	(58.2, 70.2)
Moderate	244	44 (18.0)	(13.4, 23.4)	261	40 (15.3)	(11.2, 20.3)
Severe	244	2 (0.8)	(0.1, 2.9)	261	3 (1.1)	(0.2, 3.3)
Grade 4	244	0	(0.0, 1.5)	261	0	(0.0, 1.4)
Any local reaction[f]	244	192 (78.7)	(73.0, 83.7)	261	214 (82.0)	(76.8, 86.5)

Table 10. Local Reactions, by Maximum Severity, Within 7 Days After First Study Vaccination, by Baseline SARS-CoV-2 Status - Cohort 2 - Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 OMI (30 µg)			BNT162b2 (30 µg)		
Local Reaction	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])

Abbreviation: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Reactions were collected in the e-diary from Day 1 through Day 7 after the first study vaccination.
Note: Grade 4 reactions were classified by the investigator or a medically qualified person.
Note: Positive = positive N-binding antibody result at baseline, positive NAAT result at baseline, or medical history of COVID-19. Negative = negative N-binding antibody result at baseline, negative NAAT result at baseline, and no medical history of COVID-19.
a. N = number of participants reporting at least 1 yes or no response for the specified reaction after the first study vaccination.
b. n = Number of participants 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: 08APR2022 (22:11) Source Data: adfacevd Table Generation: 19MAY2022 (01:38)
(Data Cutoff Date: 11MAR2022, Database Snapshot Date: 8APR2022) Output File: ./nda2_ubd/C4591031_D/adce_s010_lr_bas

Table 11. Systemic Events, by Maximum Severity, Within 7 Days After First Study Vaccination, by Baseline SARS-CoV-2 Status - Cohort 2 - Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 OMI (30 µg)			BNT162b2 (30 µg)		
Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Fever						
≥38.0°C	50	2 (4.0)	(0.5, 13.7)	45	1 (2.2)	(0.1, 11.8)
≥38.0°C to 38.4°C	50	0	(0.0, 7.1)	45	1 (2.2)	(0.1, 11.8)
>38.4°C to 38.9°C	50	2 (4.0)	(0.5, 13.7)	45	0	(0.0, 7.9)
>38.9°C to 40.0°C	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
>40.0°C	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
Fatigue[d]						
Any	50	35 (70.0)	(55.4, 82.1)	45	20 (44.4)	(29.6, 60.0)
Mild	50	13 (26.0)	(14.6, 40.3)	45	8 (17.8)	(8.0, 32.1)
Moderate	50	19 (38.0)	(24.7, 52.8)	45	11 (24.4)	(12.9, 39.5)
Severe	50	3 (6.0)	(1.3, 16.5)	45	1 (2.2)	(0.1, 11.8)
Grade 4	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
Headache[d]						
Any	50	22 (44.0)	(30.0, 58.7)	45	21 (46.7)	(31.7, 62.1)
Mild	50	12 (24.0)	(13.1, 38.2)	45	11 (24.4)	(12.9, 39.5)
Moderate	50	9 (18.0)	(8.6, 31.4)	45	9 (20.0)	(9.6, 34.6)
Severe	50	1 (2.0)	(0.1, 10.6)	45	1 (2.2)	(0.1, 11.8)
Grade 4	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
Chills[d]						
Any	50	16 (32.0)	(19.5, 46.7)	45	12 (26.7)	(14.6, 41.9)
Mild	50	5 (10.0)	(3.3, 21.8)	45	7 (15.6)	(6.5, 29.5)
Moderate	50	9 (18.0)	(8.6, 31.4)	45	5 (11.1)	(3.7, 24.1)
Severe	50	2 (4.0)	(0.5, 13.7)	45	0	(0.0, 7.9)
Grade 4	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)

Table 11. Systemic Events, by Maximum Severity, Within 7 Days After First Study Vaccination, by Baseline SARS-CoV-2 Status - Cohort 2 - Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 OMI (30 µg)			BNT162b2 (30 µg)		
Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Vomiting[e]						
Any	50	2 (4.0)	(0.5, 13.7)	45	0	(0.0, 7.9)
Mild	50	2 (4.0)	(0.5, 13.7)	45	0	(0.0, 7.9)
Moderate	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
Severe	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
Grade 4	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
Diarrhea[f]						
Any	50	7 (14.0)	(5.8, 26.7)	45	3 (6.7)	(1.4, 18.3)
Mild	50	7 (14.0)	(5.8, 26.7)	45	1 (2.2)	(0.1, 11.8)
Moderate	50	0	(0.0, 7.1)	45	2 (4.4)	(0.5, 15.1)
Severe	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
Grade 4	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
New or worsened muscle pain[d]						
Any	50	19 (38.0)	(24.7, 52.8)	45	10 (22.2)	(11.2, 37.1)
Mild	50	4 (8.0)	(2.2, 19.2)	45	8 (17.8)	(8.0, 32.1)
Moderate	50	15 (30.0)	(17.9, 44.6)	45	2 (4.4)	(0.5, 15.1)
Severe	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
Grade 4	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
New or worsened joint pain[d]						
Any	50	13 (26.0)	(14.6, 40.3)	45	2 (4.4)	(0.5, 15.1)
Mild	50	8 (16.0)	(7.2, 29.1)	45	0	(0.0, 7.9)
Moderate	50	4 (8.0)	(2.2, 19.2)	45	2 (4.4)	(0.5, 15.1)
Severe	50	1 (2.0)	(0.1, 10.6)	45	0	(0.0, 7.9)
Grade 4	50	0	(0.0, 7.1)	45	0	(0.0, 7.9)
Any systemic event[g]	50	38 (76.0)	(61.8, 86.9)	45	28 (62.2)	(46.5, 76.2)

Table 11. Systemic Events, by Maximum Severity, Within 7 Days After First Study Vaccination, by Baseline SARS-CoV-2 Status - Cohort 2 - Safety Population Baseline SARS-CoV-2 Status: Positive

	Vaccine Group (as Administered)					
	BNT162b2 OMI (30 µg)			BNT162b2 (30 µg)		
Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Use of antipyretic or pain medication[h]	50	20 (40.0)	(26.4, 54.8)	45	15 (33.3)	(20.0, 49.0)

Abbreviation: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Events and use of antipyretic or pain medication were collected in the e-diary from Day 1 through Day 7 after the first study vaccination.
Note: Grade 4 events were classified by the investigator or a medically qualified person.
Note: Positive = positive N-binding antibody result at baseline, positive NAAT result at baseline, or medical history of COVID-19. Negative = negative N-binding antibody result at baseline, negative NAAT result at baseline, and no medical history of COVID-19.
a. N = number of participants reporting at least 1 yes or no response for the specified event after the first study vaccination.
b. n = Number of participants 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 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.
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Table 12. Systemic Events, by Maximum Severity, Within 7 Days After First Study Vaccination, by Baseline SARS-CoV-2 Status - Cohort 2 - Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 OMI (30 µg)			BNT162b2 (30 µg)		
Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Fever						
≥38.0°C	244	23 (9.4)	(6.1, 13.8)	261	21 (8.0)	(5.0, 12.0)
≥38.0°C to 38.4°C	244	14 (5.7)	(3.2, 9.4)	261	11 (4.2)	(2.1, 7.4)
>38.4°C to 38.9°C	244	8 (3.3)	(1.4, 6.4)	261	9 (3.4)	(1.6, 6.4)
>38.9°C to 40.0°C	244	1 (0.4)	(0.0, 2.3)	261	1 (0.4)	(0.0, 2.1)
>40.0°C	244	0	(0.0, 1.5)	261	0	(0.0, 1.4)
Fatigue[d]						
Any	244	154 (63.1)	(56.7, 69.2)	261	165 (63.2)	(57.1, 69.1)
Mild	244	64 (26.2)	(20.8, 32.2)	261	81 (31.0)	(25.5, 37.0)
Moderate	244	83 (34.0)	(28.1, 40.3)	261	77 (29.5)	(24.0, 35.4)
Severe	244	7 (2.9)	(1.2, 5.8)	261	7 (2.7)	(1.1, 5.4)
Grade 4	244	0	(0.0, 1.5)	261	0	(0.0, 1.4)
Headache[d]						
Any	244	118 (48.4)	(41.9, 54.8)	261	117 (44.8)	(38.7, 51.1)
Mild	244	68 (27.9)	(22.3, 33.9)	261	68 (26.1)	(20.8, 31.8)
Moderate	244	45 (18.4)	(13.8, 23.9)	261	44 (16.9)	(12.5, 22.0)
Severe	244	5 (2.0)	(0.7, 4.7)	261	5 (1.9)	(0.6, 4.4)
Grade 4	244	0	(0.0, 1.5)	261	0	(0.0, 1.4)
Chills[d]						
Any	244	77 (31.6)	(25.8, 37.8)	261	68 (26.1)	(20.8, 31.8)
Mild	244	34 (13.9)	(9.8, 18.9)	261	39 (14.9)	(10.8, 19.9)
Moderate	244	41 (16.8)	(12.3, 22.1)	261	26 (10.0)	(6.6, 14.3)
Severe	244	2 (0.8)	(0.1, 2.9)	261	3 (1.1)	(0.2, 3.3)
Grade 4	244	0	(0.0, 1.5)	261	0	(0.0, 1.4)

Table 12. Systemic Events, by Maximum Severity, Within 7 Days After First Study Vaccination, by Baseline SARS-CoV-2 Status - Cohort 2 - Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 OMI (30 µg)			BNT162b2 (30 µg)		
Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Vomiting[e]						
Any	244	6 (2.5)	(0.9, 5.3)	261	5 (1.9)	(0.6, 4.4)
Mild	244	5 (2.0)	(0.7, 4.7)	261	5 (1.9)	(0.6, 4.4)
Moderate	244	1 (0.4)	(0.0, 2.3)	261	0	(0.0, 1.4)
Severe	244	0	(0.0, 1.5)	261	0	(0.0, 1.4)
Grade 4	244	0	(0.0, 1.5)	261	0	(0.0, 1.4)
Diarrhea[f]						
Any	244	18 (7.4)	(4.4, 11.4)	261	33 (12.6)	(8.9, 17.3)
Mild	244	15 (6.1)	(3.5, 9.9)	261	28 (10.7)	(7.2, 15.1)
Moderate	244	3 (1.2)	(0.3, 3.6)	261	3 (1.1)	(0.2, 3.3)
Severe	244	0	(0.0, 1.5)	261	2 (0.8)	(0.1, 2.7)
Grade 4	244	0	(0.0, 1.5)	261	0	(0.0, 1.4)
New or worsened muscle pain[d]						
Any	244	80 (32.8)	(26.9, 39.1)	261	77 (29.5)	(24.0, 35.4)
Mild	244	38 (15.6)	(11.3, 20.7)	261	43 (16.5)	(12.2, 21.5)
Moderate	244	40 (16.4)	(12.0, 21.6)	261	31 (11.9)	(8.2, 16.4)
Severe	244	2 (0.8)	(0.1, 2.9)	261	3 (1.1)	(0.2, 3.3)
Grade 4	244	0	(0.0, 1.5)	261	0	(0.0, 1.4)
New or worsened joint pain[d]						
Any	244	56 (23.0)	(17.8, 28.7)	261	44 (16.9)	(12.5, 22.0)
Mild	244	22 (9.0)	(5.7, 13.3)	261	24 (9.2)	(6.0, 13.4)
Moderate	244	32 (13.1)	(9.1, 18.0)	261	20 (7.7)	(4.7, 11.6)
Severe	244	2 (0.8)	(0.1, 2.9)	261	0	(0.0, 1.4)
Grade 4	244	0	(0.0, 1.5)	261	0	(0.0, 1.4)
Any systemic event[g]	244	190 (77.9)	(72.1, 82.9)	261	195 (74.7)	(69.0, 79.9)

Table 12. Systemic Events, by Maximum Severity, Within 7 Days After First Study Vaccination, by Baseline SARS-CoV-2 Status - Cohort 2 - Safety Population Baseline SARS-CoV-2 Status: Negative

	Vaccine Group (as Administered)					
	BNT162b2 OMI (30 µg)			BNT162b2 (30 µg)		
Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
Use of antipyretic or pain medication[h]	244	94 (38.5)	(32.4, 44.9)	261	106 (40.6)	(34.6, 46.8)

Abbreviation: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Events and use of antipyretic or pain medication were collected in the e-diary from Day 1 through Day 7 after the first study vaccination.
Note: Grade 4 events were classified by the investigator or a medically qualified person.
Note: Positive = positive N-binding antibody result at baseline, positive NAAT result at baseline, or medical history of COVID-19. Negative = negative N-binding antibody result at baseline, negative NAAT result at baseline, and no medical history of COVID-19.
a. N = number of participants reporting at least 1 yes or no response for the specified event after the first study vaccination.
b. n = Number of participants 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 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.
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APPENDIX 8 CHARACTERISATION OF IMPORTANT RISKS

Characterisation of Important Identified Risks and Important Potential Risks[1]

Table 1. Important Identified Risk: Anaphylaxis

Search criteria (MedDRA version 25.0): PTs Anaphylactic reaction; Anaphylactic shock; Anaphylactoid reaction; Anaphylactoid shock.	
Potential mechanisms, evidence source and strength of evidence	Interaction of an allergen with IgE on basophils and mast cells triggers release of histamine, leukotrienes and other mediators that cause diffuse smooth muscle contraction and vasodilation with plasma leakage. This can manifest clinically with dyspnea, hypotension, swelling (sometimes leading to airway compromise), and rash (including hives).
Risk factors and risk groups	Known hypersensitivity to any components of the vaccine. As IgE hypersensitivity is known to occur at re-challenge with the allergen in sensitized individuals, the risk of anaphylactic reactions following a third exposure to the same substance is anticipated to be lower in individuals without history of hypersensitivity response to first or second exposure.[2]
Preventability	Prevention of anaphylaxis may not be possible, particularly with the first dose of a vaccine; therefore, healthcare professionals administering the vaccine must be vigilant for early signs and symptoms.
Impact on the risk-benefit balance of the biologic product	Anaphylactic reaction in an individual can be impactful (medically important) because it is a potentially life-threatening event requiring medical intervention.
Public health impact	Minimal due to rarity of the event. Although the potential clinical consequences of an anaphylactic reaction are severe, this is a known risk of vaccines to healthcare professionals with negligible public health impact.

Abbreviations: IgE: Immunoglobulin E.

[1] According to EU-RMP version 5.0 in effect at the end of the reporting period. The search criteria have been updated as per MedDRA upversioning to version 25.0.

[2] https://www.ncbi.nlm.nih.gov/books/NBK560561/

Table 2. Important Identified Risk: Myocarditis and Pericarditis

Search criteria (MedDRA version 25.0)[3]: PTs Autoimmune myocarditis; Carditis; Chronic myocarditis; Eosinophilic myocarditis; Giant cell myocarditis; Hypersensitivity myocarditis; Immune-mediated myocarditis; Myocarditis; Myopericarditis; Autoimmune pericarditis; Pericarditis; Pericarditis adhesive; Pericarditis constrictive; Pleuropericarditis.	
Potential mechanisms, evidence source and strength of evidence	A MOA by which the vaccine could cause myocarditis and pericarditis has not been established. Nonclinical studies, protein sequence analyses and animal studies in rats and non-human primates have not identified a MOA. Hypotheses for MOA include an immune stimulated response (including the possibility of molecular mimicry), a general systemic inflammatory response from vaccination or a hypersensitivity response.
Risk factors and risk groups	Post-authorization reports have been received for more males than females, over a wide age range and following dose 1 and dose 2 of the vaccine. Evaluation by the EU and US CDC has found reports to be most frequent in adolescent and young adult male patients following the second dose of vaccine.
Preventability	Due to an unknown MOA, preventative measures cannot be indicated.
Impact on the risk-benefit balance of the biologic product	The vaccine continues to have a favourable risk benefit balance.
Public health impact	Considering the low rates of myocarditis and pericarditis reported following vaccination, balanced with the risk of death and illness (including myocarditis) caused by SARS-CoV-2, the public health impact of post-vaccination myocarditis and pericarditis is minimal.

Abbreviations: CDC: Centres for Disease Control and Prevention; EU: European Union; MOA: mechanism of action; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2; US: United States.

[3] The SMQ (narrow) Noninfectious myocarditis/pericarditis that became available upon the upversioning to MedDRA v. 25.0 is used as search criteria. Three new PTs (Carditis, Chronic myocarditis and Myopericarditis) are included in the search criteria for myocarditis, compared to the criteria specified for myocarditis in the EU-RMP v 5.0.

Table 3. Important Potential Risk Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)

Search criteria (MedDRA version 25.0): *1. PTs Vaccine associated enhanced respiratory disease OR Vaccine associated enhanced disease* *OR* *2. Standard Decreased Therapeutic Response Search AND at least 1 of the following PTs* *Abdominal pain; Acute hepatic failure; Acute kidney injury; Acute myocardial infarction; Acute respiratory distress syndrome; Altered state of consciousness; Arrhythmia; Cardiac failure; Cardiogenic shock; Cerebrovascular accident; Chilblains; COVID-19 pneumonia; Deep vein thrombosis; Diarrhoea; Disseminated intravascular coagulation; Dyspnoea; Encephalopathy; Erythema multiforme; Hypoxia; Jaundice; Meningitis; Multiple organ dysfunction syndrome; Multisystem inflammatory syndrome in children; Myocarditis; Peripheral ischaemia; Pulmonary embolism; Renal failure; Respiratory failure; Seizure; Shock; Tachypnoea; Vasculitis; Vomiting; Thrombocytopenia.*	
Potential mechanisms, evidence source and strength of evidence	This potential risk is theoretical because it has not been described in association with the COVID-19 mRNA vaccine or it has not been reported from any other late phase clinical trial of other human vaccine. Animal models of SARS-CoV-2 infection have not shown evidence of VAED after immunisation, whereas cellular immunopathology has been demonstrated after viral challenge in some animal models administered SARS-CoV-1 (murine, ferret and non-human primate models) or MERS-CoV (mice model) vaccines.[4,5] This potential risk has been included based on these animal data with these related betacoronaviruses. Historically, disease enhancement in vaccinated children following infection with natural virus has been observed with an inactivated respiratory syncytial virus vaccine.[6] Potential mechanisms of enhanced disease may include both T cell-mediated [an immunopathological response favouring T_h2 over T_h1] and antibody-mediated immune responses (antibody responses with insufficient neutralizing activity leading to formation of immune complexes and activation of complement or allowing for Fc-mediated increase in viral entry to cells).[7]
Risk factors and risk groups	It is postulated that the potential risk may be increased in individuals producing lower neutralizing antibody titers or in those demonstrating waning immunity.[7]
Preventability	An effective vaccine against COVID-19 that produces high neutralizing titers and a T_H1 predominant $CD4^+$ T cell response and strong $CD8^+$ T cell response, is expected to mitigate the risk of VAED/VAERD;[4,7] that immune profile is elicited by COVID-19 mRNA vaccine in clinical and preclinical studies.[8,9]

[4] Lambert PH, Ambrosino DM, Andersen SR, et al. Consensus summary report for CEPI/BC March 12–13, 2020 meeting: Assessment of risk of disease enhancement with COVID-19 vaccines. Vaccine 2020;38(31):4783-91.

[5] Haynes BF, Corey L, Fernandes P, et al. Prospects for a safe COVID-19 vaccine. Sci Transl Med 2020;12(568):eabe0948.

[6] Openshaw PJ, Culley FJ, Olszewska W. Immunopathogenesis of vaccine-enhanced RSV disease. Vaccine 2001;20(Suppl 1):S27-31.

[7] Graham BS. Rapid COVID-19 vaccine development. Science 2020;368(6494):945-6.

[8] Sahin U, Muik A, Derhovanessian E, et al. Concurrent human antibody and TH1 type T-cell responses elicited by a COVID-19 RNA vaccine. medRxiv 2020.07.17.20140533.

[9] Vogel AB, Kanevsky I, Che Ye, et al. A prefusion SARS-CoV-2 spike RNA vaccine is highly immunogenic and prevents lung infection in non-human primates. bioRxiv 2020.09.08.280818.

Table 3. Important Potential Risk Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)

Impact on the risk-benefit balance of the biologic product	If there were an unfavourable balance in COVID-19 cases, including severe cases, in the pivotal clinical study between the vaccine and placebo groups, that may signal VAED/VAERD.
Public health impact	The potential risk of VAED/VAERD could have a public health impact if large populations of individuals are affected.

Abbreviations: CD4, CD8: cluster of differentiation-4,8; COVID-19: coronavirus disease 2019; MERS-CoV: middle East respiratory syndrome coronavirus; mRNA: messenger ribonucleic acid; SARS-CoV-1: severe acute respiratory syndrome coronavirus 1; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2; T_h1: T helper cell type 1; T_h2: T helper cell type 2.