

Pfizer-BioNTech COVID-19 Vaccine

EUA 27034

**Response to May 5, 2021 CBER Information Request Regarding
Emergency Use Authorization for Individuals 12 to 15 Years of Age**

May 6, 2021

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1. INTRODUCTION

Reference is made to the amendment 132 (dated April 9, 2021) to EUA 27034 to extend the emergency use authorization of the Pfizer-BioNTech COVID-19 Vaccine to individuals 12 through 15 years of age.

The purpose of this document is to respond to CBER's request (received on May 5, 2021) for subgroup analyses of solicited local reactions and systemic events based on sex (M/F), race, and ethnicity in adolescents 12 through 15 years of age.

CBER's request is shown in ***bold italics*** followed by the Sponsor's response in plain text.

2. CBER REQUEST AND PFIZER RESPONSE

Please provide subgroup analyses of solicited local reactions and systemic AEs, based on sex (M/F), race, and ethnicity, in adolescents 12 through 15 years of age.

Sponsor Response

The requested analyses are presented in tables and summarized below by subgroup category.

Reactogenicity by Sex Subgroup

Local reactions ([Table 1](#)) after Dose 1 and Dose 2 varied between male and female adolescents where redness was slightly higher in males compared to females (6.9% and 7.7% vs 4.6% and 2.4%, respectively), pain at the injection site was slightly higher in females compared to males after Dose 1 and Dose 2 (89.0% and 82.1% vs 83.4% and 75.8%, respectively), while swelling was similar between the sexes. However, these small differences are unlikely to be clinically significant on a population basis. When comparing any local reactions there was a slight increase in redness for males compared to females but similar frequencies for swelling and pain at the injection site.

Systemic events ([Table 2](#)) were generally similar between male and female adolescents after the first dose. After the second dose there was slightly higher frequency of fatigue (68.5% vs 63.9%, respectively), muscle pain (35.1% vs 29.5%, respectively) and joint pain (17.6% vs 13.9%, respectively) in females compared to males. However, these slight differences are unlikely to be clinically meaningful in a mass vaccination program. In a comparison of any systemic reactions the frequencies were generally similar between the sexes.

Systemic events analyzed by sex generally followed the same pattern as has been observed in individuals 16 years and older, namely that subjects in the BNT162b2 group tend to experience more reactogenicity following the second dose compared to the first dose.

Reactogenicity by Race Subgroup

Note that the number of subjects was small in subgroups of Black or African American (N=50), Asian (N=71), and Other (N=36) race categories, and so their subgroup data should be interpreted with caution.

Local reactions ([Table 3](#)) after Any dose were generally similar between adolescents within the White, Black or African American, Asian, and Other race subgroups. The Black or African American subgroup of BNT162b2 recipients reported more swelling and less pain at the injection site after each dose relative to other race subgroups, with frequencies of both reactions decreasing after Dose 2 as compared with Dose 1.

As has been previously observed in individuals 16 years and older, the frequency of most systemic events ([Table 4](#)) tended to increase after Dose 2 relative to after Dose 1 of BNT162b2. This was less consistent in the smaller subgroups of Black or African American (N=50) and Other (N=36) subgroups, in which frequencies for some systemic events remained generally the same or decreased from after Dose 1 to after Dose 2 of BNT162b2. Fatigue and headache were reported at lower frequencies in the Black or African American subgroup compared with other subgroups and were similar following each dose. However, when systemic reactions were compared after any dose the rates were similar between the racial subgroups with Black or African American reporting lower rates of systemic events.

Reactogenicity by Ethnicity Subgroup

Local reactions ([Table 5](#)) were generally similar between Hispanic/Latino and non-Hispanic/non-Latino adolescents. Local reactions in these subgroups occurred at a lower frequency following the second dose, relative to the first dose.

The frequency of most systemic events ([Table 6](#)) tended to increase after Dose 2 relative to after Dose 1 of BNT162b2 for subgroups of Hispanic/Latino and non-Hispanic/non-Latino adolescents, similar to the previously observed pattern.

Overall Conclusions

Overall, adolescents 12 to 15 years of age had no clinically important differences in their reactogenicity profiles on the basis of sex, race, or ethnicity subgroups. Local reactions usually occurred at either similar or lower frequencies in some subgroups, compared with the other subgroups, as has been typically observed in adolescents in general. Systemic events tended to follow the established pattern for the BNT162b2 dosing regimen, typically reported at higher frequencies after the second dose than after the first, and in several cases reported at similar or lower frequencies for some subgroups after one or both doses. In line with the previously submitted reactogenicity subset analysis for all adolescents, these additional data support a tolerable reactogenicity profile across adolescent subgroups.

Table 1. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

Sex	Dose	Local Reaction	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI ^c)	N ^a	Placebo n ^b (%)	(95% CI ^c)
Male	1	Redness ^d						
		Any	565	39 (6.9)	(5.0, 9.3)	583	6 (1.0)	(0.4, 2.2)
		Mild	565	27 (4.8)	(3.2, 6.9)	583	6 (1.0)	(0.4, 2.2)
		Moderate	565	11 (1.9)	(1.0, 3.5)	583	0	(0.0, 0.6)
		Severe	565	1 (0.2)	(0.0, 1.0)	583	0	(0.0, 0.6)
		Grade 4	565	0	(0.0, 0.7)	583	0	(0.0, 0.6)
		Swelling ^d						
		Any	565	38 (6.7)	(4.8, 9.1)	583	3 (0.5)	(0.1, 1.5)
		Mild	565	25 (4.4)	(2.9, 6.5)	583	3 (0.5)	(0.1, 1.5)
		Moderate	565	13 (2.3)	(1.2, 3.9)	583	0	(0.0, 0.6)
		Severe	565	0	(0.0, 0.7)	583	0	(0.0, 0.6)
		Grade 4	565	0	(0.0, 0.7)	583	0	(0.0, 0.6)
		Pain at the injection site ^e						
		Any	565	471 (83.4)	(80.0, 86.3)	583	98 (16.8)	(13.9, 20.1)
		Mild	565	257 (45.5)	(41.3, 49.7)	583	88 (15.1)	(12.3, 18.3)
		Moderate	565	212 (37.5)	(33.5, 41.7)	583	10 (1.7)	(0.8, 3.1)
		Severe	565	2 (0.4)	(0.0, 1.3)	583	0	(0.0, 0.6)
		Grade 4	565	0	(0.0, 0.7)	583	0	(0.0, 0.6)
		Any local reaction ^f	565	474 (83.9)	(80.6, 86.8)	583	101 (17.3)	(14.3, 20.6)
	2	Redness ^d						
		Any	545	42 (7.7)	(5.6, 10.3)	563	3 (0.5)	(0.1, 1.5)
		Mild	545	22 (4.0)	(2.5, 6.0)	563	2 (0.4)	(0.0, 1.3)

Table 1. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

			Vaccine Group (as Administered)					
Sex	Dose	Local Reaction	BNT162b2 (30 µg)			Placebo		
			N ^a	n ^b (%)	(95% CI ^c)	N ^a	n ^b (%)	(95% CI ^c)
	Any dose	Moderate	545	20 (3.7)	(2.3, 5.6)	563	1 (0.2)	(0.0, 1.0)
		Severe	545	0	(0.0, 0.7)	563	0	(0.0, 0.7)
		Grade 4	545	0	(0.0, 0.7)	563	0	(0.0, 0.7)
		Swelling ^d						
		Any	545	32 (5.9)	(4.1, 8.2)	563	2 (0.4)	(0.0, 1.3)
		Mild	545	21 (3.9)	(2.4, 5.8)	563	2 (0.4)	(0.0, 1.3)
		Moderate	545	11 (2.0)	(1.0, 3.6)	563	0	(0.0, 0.7)
		Severe	545	0	(0.0, 0.7)	563	0	(0.0, 0.7)
		Grade 4	545	0	(0.0, 0.7)	563	0	(0.0, 0.7)
		Pain at the injection site ^e						
		Any	545	413 (75.8)	(72.0, 79.3)	563	70 (12.4)	(9.8, 15.4)
		Mild	545	234 (42.9)	(38.7, 47.2)	563	56 (9.9)	(7.6, 12.7)
		Moderate	545	176 (32.3)	(28.4, 36.4)	563	14 (2.5)	(1.4, 4.1)
		Severe	545	3 (0.6)	(0.1, 1.6)	563	0	(0.0, 0.7)
		Grade 4	545	0	(0.0, 0.7)	563	0	(0.0, 0.7)
		Any local reaction ^f	545	417 (76.5)	(72.7, 80.0)	563	71 (12.6)	(10.0, 15.6)
		Redness ^d						
		Any	567	65 (11.5)	(9.0, 14.4)	585	8 (1.4)	(0.6, 2.7)
		Mild	567	37 (6.5)	(4.6, 8.9)	585	7 (1.2)	(0.5, 2.4)
		Moderate	567	27 (4.8)	(3.2, 6.9)	585	1 (0.2)	(0.0, 0.9)
		Severe	567	1 (0.2)	(0.0, 1.0)	585	0	(0.0, 0.6)
		Grade 4	567	0	(0.0, 0.6)	585	0	(0.0, 0.6)
				Swelling ^d				

Table 1. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

			Vaccine Group (as Administered)					
Sex	Dose	Local Reaction	BNT162b2 (30 µg)			Placebo		
			N ^a	n ^b (%)	(95% CI ^c)	N ^a	n ^b (%)	(95% CI ^c)
Female	1	Any	567	53 (9.3)	(7.1, 12.0)	585	4 (0.7)	(0.2, 1.7)
		Mild	567	33 (5.8)	(4.0, 8.1)	585	4 (0.7)	(0.2, 1.7)
		Moderate	567	20 (3.5)	(2.2, 5.4)	585	0	(0.0, 0.6)
		Severe	567	0	(0.0, 0.6)	585	0	(0.0, 0.6)
		Grade 4	567	0	(0.0, 0.6)	585	0	(0.0, 0.6)
		Pain at the injection site ^c						
		Any	567	502 (88.5)	(85.6, 91.0)	585	133 (22.7)	(19.4, 26.3)
		Mild	567	219 (38.6)	(34.6, 42.8)	585	113 (19.3)	(16.2, 22.8)
		Moderate	567	278 (49.0)	(44.8, 53.2)	585	20 (3.4)	(2.1, 5.2)
		Severe	567	5 (0.9)	(0.3, 2.0)	585	0	(0.0, 0.6)
		Grade 4	567	0	(0.0, 0.6)	585	0	(0.0, 0.6)
		Any local reaction ^f	567	506 (89.2)	(86.4, 91.7)	585	136 (23.2)	(19.9, 26.9)
		Redness ^d						
		Any	562	26 (4.6)	(3.0, 6.7)	544	6 (1.1)	(0.4, 2.4)
		Mild	562	17 (3.0)	(1.8, 4.8)	544	5 (0.9)	(0.3, 2.1)
		Moderate	562	9 (1.6)	(0.7, 3.0)	544	1 (0.2)	(0.0, 1.0)
		Severe	562	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Grade 4	562	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Swelling ^d						
		Any	562	40 (7.1)	(5.1, 9.6)	544	8 (1.5)	(0.6, 2.9)
		Mild	562	30 (5.3)	(3.6, 7.5)	544	6 (1.1)	(0.4, 2.4)
		Moderate	562	10 (1.8)	(0.9, 3.2)	544	2 (0.4)	(0.0, 1.3)
		Severe	562	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Grade 4	562	0	(0.0, 0.7)	544	0	(0.0, 0.7)

Table 1. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

Sex	Dose	Local Reaction	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI ^c)	N ^a	Placebo n ^b (%)	(95% CI ^c)
2		Pain at the injection site ^e						
		Any	562	500 (89.0)	(86.1, 91.4)	544	165 (30.3)	(26.5, 34.4)
		Mild	562	210 (37.4)	(33.4, 41.5)	544	139 (25.6)	(21.9, 29.4)
		Moderate	562	281 (50.0)	(45.8, 54.2)	544	26 (4.8)	(3.1, 6.9)
		Severe	562	9 (1.6)	(0.7, 3.0)	544	0	(0.0, 0.7)
		Grade 4	562	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Any local reaction ^f	562	502 (89.3)	(86.5, 91.8)	544	170 (31.3)	(27.4, 35.3)
		Redness ^d						
		Any	552	13 (2.4)	(1.3, 4.0)	515	7 (1.4)	(0.5, 2.8)
		Mild	552	7 (1.3)	(0.5, 2.6)	515	6 (1.2)	(0.4, 2.5)
		Moderate	552	6 (1.1)	(0.4, 2.4)	515	1 (0.2)	(0.0, 1.1)
		Severe	552	0	(0.0, 0.7)	515	0	(0.0, 0.7)
		Grade 4	552	0	(0.0, 0.7)	515	0	(0.0, 0.7)
		Swelling ^d						
		Any	552	22 (4.0)	(2.5, 6.0)	515	4 (0.8)	(0.2, 2.0)
		Mild	552	15 (2.7)	(1.5, 4.4)	515	2 (0.4)	(0.0, 1.4)
		Moderate	552	7 (1.3)	(0.5, 2.6)	515	2 (0.4)	(0.0, 1.4)
		Severe	552	0	(0.0, 0.7)	515	0	(0.0, 0.7)
		Grade 4	552	0	(0.0, 0.7)	515	0	(0.0, 0.7)
		Pain at the injection site ^e						
		Any	552	453 (82.1)	(78.6, 85.2)	515	123 (23.9)	(20.3, 27.8)
		Mild	552	232 (42.0)	(37.9, 46.3)	515	108 (21.0)	(17.5, 24.7)
		Moderate	552	217 (39.3)	(35.2, 43.5)	515	15 (2.9)	(1.6, 4.8)

Table 1. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

			Vaccine Group (as Administered)					
Sex	Dose	Local Reaction	BNT162b2 (30 µg)			Placebo		
			N ^a	n ^b (%)	(95% CI ^c)	N ^a	n ^b (%)	(95% CI ^c)
	Any dose	Severe	552	4 (0.7)	(0.2, 1.8)	515	0	(0.0, 0.7)
		Grade 4	552	0	(0.0, 0.7)	515	0	(0.0, 0.7)
		Any local reaction ^f	552	455 (82.4)	(79.0, 85.5)	515	127 (24.7)	(21.0, 28.6)
		Redness ^d						
		Any	564	32 (5.7)	(3.9, 7.9)	544	10 (1.8)	(0.9, 3.4)
		Mild	564	18 (3.2)	(1.9, 5.0)	544	8 (1.5)	(0.6, 2.9)
		Moderate	564	14 (2.5)	(1.4, 4.1)	544	2 (0.4)	(0.0, 1.3)
		Severe	564	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Grade 4	564	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Swelling ^d						
		Any	564	51 (9.0)	(6.8, 11.7)	544	9 (1.7)	(0.8, 3.1)
		Mild	564	36 (6.4)	(4.5, 8.7)	544	6 (1.1)	(0.4, 2.4)
		Moderate	564	15 (2.7)	(1.5, 4.3)	544	3 (0.6)	(0.1, 1.6)
		Severe	564	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Grade 4	564	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Pain at the injection site ^e						
		Any	564	521 (92.4)	(89.9, 94.4)	544	208 (38.2)	(34.1, 42.5)
		Mild	564	175 (31.0)	(27.2, 35.0)	544	170 (31.3)	(27.4, 35.3)
		Moderate	564	334 (59.2)	(55.0, 63.3)	544	38 (7.0)	(5.0, 9.5)
		Severe	564	12 (2.1)	(1.1, 3.7)	544	0	(0.0, 0.7)
		Grade 4	564	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Any local reaction ^f	564	522 (92.6)	(90.1, 94.6)	544	213 (39.2)	(35.0, 43.4)

Table 1. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

Sex	Dose	Local Reaction	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg)		N ^a	Placebo	
				n ^b (%)	(95% CI ^c)		n ^b (%)	(95% CI ^c)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose.

Note: Grade 4 reactions were classified by the investigator or medically qualified person.

- N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.
- n = Number of subjects with the specified characteristic.
- Exact 2-sided CI based on the Clopper and Pearson method.
- 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).
- 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.
- Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.

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Table 2. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

Sex	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
Male	1	Fever						
		≥38.0°C	565	60 (10.6)	(8.2, 13.5)	583	9 (1.5)	(0.7, 2.9)
		≥38.0°C to 38.4°C	565	38 (6.7)	(4.8, 9.1)	583	6 (1.0)	(0.4, 2.2)
		>38.4°C to 38.9°C	565	17 (3.0)	(1.8, 4.8)	583	2 (0.3)	(0.0, 1.2)
		>38.9°C to 40.0°C	565	4 (0.7)	(0.2, 1.8)	583	1 (0.2)	(0.0, 1.0)
		>40.0°C	565	1 (0.2)	(0.0, 1.0)	583	0	(0.0, 0.6)
		Fatigue ^d						
		Any	565	333 (58.9)	(54.8, 63.0)	583	175 (30.0)	(26.3, 33.9)
		Mild	565	138 (24.4)	(20.9, 28.2)	583	100 (17.2)	(14.2, 20.5)
		Moderate	565	188 (33.3)	(29.4, 37.3)	583	70 (12.0)	(9.5, 14.9)
		Severe	565	7 (1.2)	(0.5, 2.5)	583	5 (0.9)	(0.3, 2.0)
		Grade 4	565	0	(0.0, 0.7)	583	0	(0.0, 0.6)
		Headache ^d						
		Any	565	301 (53.3)	(49.1, 57.5)	583	164 (28.1)	(24.5, 32.0)
		Mild	565	172 (30.4)	(26.7, 34.4)	583	108 (18.5)	(15.5, 21.9)
		Moderate	565	127 (22.5)	(19.1, 26.1)	583	52 (8.9)	(6.7, 11.5)
		Severe	565	2 (0.4)	(0.0, 1.3)	583	4 (0.7)	(0.2, 1.7)
		Grade 4	565	0	(0.0, 0.7)	583	0	(0.0, 0.6)
		Chills ^d						
		Any	565	164 (29.0)	(25.3, 33.0)	583	42 (7.2)	(5.2, 9.6)

Table 2. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

Sex	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)		
		Mild	565	100 (17.7)	(14.6, 21.1)	583	32 (5.5)	(3.8, 7.7)
		Moderate	565	60 (10.6)	(8.2, 13.5)	583	8 (1.4)	(0.6, 2.7)
		Severe	565	4 (0.7)	(0.2, 1.8)	583	2 (0.3)	(0.0, 1.2)
		Grade 4	565	0	(0.0, 0.7)	583	0	(0.0, 0.6)
		Vomiting ^e						
		Any	565	17 (3.0)	(1.8, 4.8)	583	3 (0.5)	(0.1, 1.5)
		Mild	565	17 (3.0)	(1.8, 4.8)	583	2 (0.3)	(0.0, 1.2)
		Moderate	565	0	(0.0, 0.7)	583	1 (0.2)	(0.0, 1.0)
		Severe	565	0	(0.0, 0.7)	583	0	(0.0, 0.6)
		Grade 4	565	0	(0.0, 0.7)	583	0	(0.0, 0.6)
		Diarrhea ^f						
		Any	565	45 (8.0)	(5.9, 10.5)	583	40 (6.9)	(4.9, 9.2)
		Mild	565	39 (6.9)	(5.0, 9.3)	583	31 (5.3)	(3.6, 7.5)
		Moderate	565	6 (1.1)	(0.4, 2.3)	583	9 (1.5)	(0.7, 2.9)
		Severe	565	0	(0.0, 0.7)	583	0	(0.0, 0.6)
		Grade 4	565	0	(0.0, 0.7)	583	0	(0.0, 0.6)
		New or worsened muscle pain ^d						
		Any	565	125 (22.1)	(18.8, 25.8)	583	58 (9.9)	(7.6, 12.7)
		Mild	565	62 (11.0)	(8.5, 13.8)	583	34 (5.8)	(4.1, 8.1)
		Moderate	565	61 (10.8)	(8.4, 13.7)	583	24 (4.1)	(2.7, 6.1)
		Severe	565	2 (0.4)	(0.0, 1.3)	583	0	(0.0, 0.6)
		Grade 4	565	0	(0.0, 0.7)	583	0	(0.0, 0.6)
		New or worsened joint pain ^d						
		Any	565	55 (9.7)	(7.4, 12.5)	583	37 (6.3)	(4.5, 8.6)

Table 2. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

Sex	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)		
	2	Mild	565	33 (5.8)	(4.1, 8.1)	583	23 (3.9)	(2.5, 5.9)
		Moderate	565	22 (3.9)	(2.5, 5.8)	583	14 (2.4)	(1.3, 4.0)
		Severe	565	0	(0.0, 0.7)	583	0	(0.0, 0.6)
		Grade 4	565	0	(0.0, 0.7)	583	0	(0.0, 0.6)
		Any systemic event ^g	565	438 (77.5)	(73.9, 80.9)	583	283 (48.5)	(44.4, 52.7)
		Use of antipyretic or pain medication ^h	565	196 (34.7)	(30.8, 38.8)	583	42 (7.2)	(5.2, 9.6)
		Fever						
		≥38.0°C	545	103 (18.9)	(15.7, 22.4)	563	6 (1.1)	(0.4, 2.3)
		≥38.0°C to 38.4°C	545	55 (10.1)	(7.7, 12.9)	563	5 (0.9)	(0.3, 2.1)
		>38.4°C to 38.9°C	545	38 (7.0)	(5.0, 9.4)	563	0	(0.0, 0.7)
		>38.9°C to 40.0°C	545	10 (1.8)	(0.9, 3.3)	563	1 (0.2)	(0.0, 1.0)
		>40.0°C	545	0	(0.0, 0.7)	563	0	(0.0, 0.7)
		Fatigue ^d						
		Any	545	348 (63.9)	(59.7, 67.9)	563	111 (19.7)	(16.5, 23.2)
		Mild	545	113 (20.7)	(17.4, 24.4)	563	62 (11.0)	(8.5, 13.9)
		Moderate	545	221 (40.6)	(36.4, 44.8)	563	47 (8.3)	(6.2, 10.9)
		Severe	545	14 (2.6)	(1.4, 4.3)	563	2 (0.4)	(0.0, 1.3)
		Grade 4	545	0	(0.0, 0.7)	563	0	(0.0, 0.7)
		Headache ^d						
		Any	545	333 (61.1)	(56.9, 65.2)	563	100 (17.8)	(14.7, 21.2)
		Mild	545	148 (27.2)	(23.5, 31.1)	563	71 (12.6)	(10.0, 15.6)
		Moderate	545	178 (32.7)	(28.7, 36.8)	563	29 (5.2)	(3.5, 7.3)
		Severe	545	7 (1.3)	(0.5, 2.6)	563	0	(0.0, 0.7)

Table 2. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

			Vaccine Group (as Administered)					
Sex	Dose	Systemic Event	BNT162b2 (30 µg)			Placebo		
			N ^a	n ^b (%)	(95% CI ^c)	N ^a	n ^b (%)	(95% CI ^c)
		Grade 4	545	0	(0.0, 0.7)	563	0	(0.0, 0.7)
		Chills ^d						
		Any	545	224 (41.1)	(36.9, 45.4)	563	25 (4.4)	(2.9, 6.5)
		Mild	545	113 (20.7)	(17.4, 24.4)	563	18 (3.2)	(1.9, 5.0)
		Moderate	545	102 (18.7)	(15.5, 22.2)	563	7 (1.2)	(0.5, 2.5)
		Severe	545	9 (1.7)	(0.8, 3.1)	563	0	(0.0, 0.7)
		Grade 4	545	0	(0.0, 0.7)	563	0	(0.0, 0.7)
		Vomiting ^e						
		Any	545	11 (2.0)	(1.0, 3.6)	563	9 (1.6)	(0.7, 3.0)
		Mild	545	9 (1.7)	(0.8, 3.1)	563	8 (1.4)	(0.6, 2.8)
		Moderate	545	2 (0.4)	(0.0, 1.3)	563	1 (0.2)	(0.0, 1.0)
		Severe	545	0	(0.0, 0.7)	563	0	(0.0, 0.7)
		Grade 4	545	0	(0.0, 0.7)	563	0	(0.0, 0.7)
		Diarrhea ^f						
		Any	545	31 (5.7)	(3.9, 8.0)	563	24 (4.3)	(2.8, 6.3)
		Mild	545	30 (5.5)	(3.7, 7.8)	563	21 (3.7)	(2.3, 5.6)
		Moderate	545	1 (0.2)	(0.0, 1.0)	563	3 (0.5)	(0.1, 1.5)
		Severe	545	0	(0.0, 0.7)	563	0	(0.0, 0.7)
		Grade 4	545	0	(0.0, 0.7)	563	0	(0.0, 0.7)
		New or worsened muscle pain ^d						
		Any	545	161 (29.5)	(25.7, 33.6)	563	29 (5.2)	(3.5, 7.3)
		Mild	545	67 (12.3)	(9.7, 15.3)	563	15 (2.7)	(1.5, 4.4)
		Moderate	545	92 (16.9)	(13.8, 20.3)	563	13 (2.3)	(1.2, 3.9)
		Severe	545	2 (0.4)	(0.0, 1.3)	563	1 (0.2)	(0.0, 1.0)

Table 2. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

			Vaccine Group (as Administered)					
Sex	Dose	Systemic Event	BNT162b2 (30 µg)			Placebo		
			N ^a	n ^b (%)	(95% CI ^c)	N ^a	n ^b (%)	(95% CI ^c)
		Grade 4	545	0	(0.0, 0.7)	563	0	(0.0, 0.7)
		New or worsened joint pain ^d						
		Any	545	76 (13.9)	(11.1, 17.1)	563	21 (3.7)	(2.3, 5.6)
		Mild	545	39 (7.2)	(5.1, 9.7)	563	10 (1.8)	(0.9, 3.2)
		Moderate	545	36 (6.6)	(4.7, 9.0)	563	11 (2.0)	(1.0, 3.5)
		Severe	545	1 (0.2)	(0.0, 1.0)	563	0	(0.0, 0.7)
		Grade 4	545	0	(0.0, 0.7)	563	0	(0.0, 0.7)
		Any systemic event ^e	545	440 (80.7)	(77.2, 84.0)	563	188 (33.4)	(29.5, 37.5)
		Use of antipyretic or pain medication ^h	545	260 (47.7)	(43.4, 52.0)	563	34 (6.0)	(4.2, 8.3)
	Any dose	Fever						
		≥38.0°C	567	133 (23.5)	(20.0, 27.2)	585	13 (2.2)	(1.2, 3.8)
		≥38.0°C to 38.4°C	567	69 (12.2)	(9.6, 15.1)	585	9 (1.5)	(0.7, 2.9)
		>38.4°C to 38.9°C	567	50 (8.8)	(6.6, 11.5)	585	2 (0.3)	(0.0, 1.2)
		>38.9°C to 40.0°C	567	13 (2.3)	(1.2, 3.9)	585	2 (0.3)	(0.0, 1.2)
		>40.0°C	567	1 (0.2)	(0.0, 1.0)	585	0	(0.0, 0.6)
		Fatigue ^d						
		Any	567	429 (75.7)	(71.9, 79.1)	585	219 (37.4)	(33.5, 41.5)
		Mild	567	117 (20.6)	(17.4, 24.2)	585	116 (19.8)	(16.7, 23.3)
		Moderate	567	291 (51.3)	(47.1, 55.5)	585	96 (16.4)	(13.5, 19.7)
		Severe	567	21 (3.7)	(2.3, 5.6)	585	7 (1.2)	(0.5, 2.4)
		Grade 4	567	0	(0.0, 0.6)	585	0	(0.0, 0.6)
		Headache ^d						
		Any	567	407 (71.8)	(67.9, 75.5)	585	209 (35.7)	(31.8, 39.8)

Table 2. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

			Vaccine Group (as Administered)					
Sex	Dose	Systemic Event	BNT162b2 (30 µg)			Placebo		
			N ^a	n ^b (%)	(95% CI ^c)	N ^a	n ^b (%)	(95% CI ^c)
		Mild	567	159 (28.0)	(24.4, 31.9)	585	132 (22.6)	(19.2, 26.2)
		Moderate	567	239 (42.2)	(38.0, 46.3)	585	73 (12.5)	(9.9, 15.4)
		Severe	567	9 (1.6)	(0.7, 3.0)	585	4 (0.7)	(0.2, 1.7)
		Grade 4	567	0	(0.0, 0.6)	585	0	(0.0, 0.6)
		Chills ^d						
		Any	567	273 (48.1)	(44.0, 52.3)	585	62 (10.6)	(8.2, 13.4)
		Mild	567	124 (21.9)	(18.5, 25.5)	585	45 (7.7)	(5.7, 10.2)
		Moderate	567	137 (24.2)	(20.7, 27.9)	585	15 (2.6)	(1.4, 4.2)
		Severe	567	12 (2.1)	(1.1, 3.7)	585	2 (0.3)	(0.0, 1.2)
		Grade 4	567	0	(0.0, 0.6)	585	0	(0.0, 0.6)
		Vomiting ^e						
		Any	567	28 (4.9)	(3.3, 7.1)	585	12 (2.1)	(1.1, 3.6)
		Mild	567	26 (4.6)	(3.0, 6.6)	585	10 (1.7)	(0.8, 3.1)
		Moderate	567	2 (0.4)	(0.0, 1.3)	585	2 (0.3)	(0.0, 1.2)
		Severe	567	0	(0.0, 0.6)	585	0	(0.0, 0.6)
		Grade 4	567	0	(0.0, 0.6)	585	0	(0.0, 0.6)
		Diarrhea ^f						
		Any	567	68 (12.0)	(9.4, 15.0)	585	54 (9.2)	(7.0, 11.9)
		Mild	567	61 (10.8)	(8.3, 13.6)	585	42 (7.2)	(5.2, 9.6)
		Moderate	567	7 (1.2)	(0.5, 2.5)	585	12 (2.1)	(1.1, 3.6)
		Severe	567	0	(0.0, 0.6)	585	0	(0.0, 0.6)
		Grade 4	567	0	(0.0, 0.6)	585	0	(0.0, 0.6)
		New or worsened muscle pain ^d						
		Any	567	220 (38.8)	(34.8, 42.9)	585	76 (13.0)	(10.4, 16.0)

Table 2. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

			Vaccine Group (as Administered)					
Sex	Dose	Systemic Event	BNT162b2 (30 µg)			Placebo		
			N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
Female	1	Mild	567	90 (15.9)	(13.0, 19.1)	585	43 (7.4)	(5.4, 9.8)
		Moderate	567	126 (22.2)	(18.9, 25.9)	585	32 (5.5)	(3.8, 7.6)
		Severe	567	4 (0.7)	(0.2, 1.8)	585	1 (0.2)	(0.0, 0.9)
		Grade 4	567	0	(0.0, 0.6)	585	0	(0.0, 0.6)
		New or worsened joint pain ^d						
		Any	567	109 (19.2)	(16.1, 22.7)	585	50 (8.5)	(6.4, 11.1)
		Mild	567	58 (10.2)	(7.9, 13.0)	585	27 (4.6)	(3.1, 6.6)
		Moderate	567	50 (8.8)	(6.6, 11.5)	585	23 (3.9)	(2.5, 5.8)
		Severe	567	1 (0.2)	(0.0, 1.0)	585	0	(0.0, 0.6)
		Grade 4	567	0	(0.0, 0.6)	585	0	(0.0, 0.6)
		Any systemic event ^g	567	514 (90.7)	(88.0, 92.9)	585	329 (56.2)	(52.1, 60.3)
		Use of antipyretic or pain medication ^h	567	317 (55.9)	(51.7, 60.0)	585	64 (10.9)	(8.5, 13.8)
		Fever						
		≥38.0°C	562	54 (9.6)	(7.3, 12.4)	544	3 (0.6)	(0.1, 1.6)
		≥38.0°C to 38.4°C	562	36 (6.4)	(4.5, 8.8)	544	2 (0.4)	(0.0, 1.3)
		>38.4°C to 38.9°C	562	12 (2.1)	(1.1, 3.7)	544	0	(0.0, 0.7)
		>38.9°C to 40.0°C	562	6 (1.1)	(0.4, 2.3)	544	1 (0.2)	(0.0, 1.0)
		>40.0°C	562	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Fatigue ^d						
		Any	562	344 (61.2)	(57.0, 65.3)	544	282 (51.8)	(47.5, 56.1)
		Mild	562	140 (24.9)	(21.4, 28.7)	544	150 (27.6)	(23.9, 31.5)
		Moderate	562	196 (34.9)	(30.9, 39.0)	544	129 (23.7)	(20.2, 27.5)
		Severe	562	8 (1.4)	(0.6, 2.8)	544	3 (0.6)	(0.1, 1.6)

Table 2. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

Sex	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg)		N ^a	Placebo	
				n ^b (%)	(95% CI ^c)		n ^b (%)	(95% CI ^c)
		Grade 4	562	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Headache ^d						
		Any	562	322 (57.3)	(53.1, 61.4)	544	232 (42.6)	(38.4, 46.9)
		Mild	562	189 (33.6)	(29.7, 37.7)	544	148 (27.2)	(23.5, 31.2)
		Moderate	562	124 (22.1)	(18.7, 25.7)	544	79 (14.5)	(11.7, 17.8)
		Severe	562	9 (1.6)	(0.7, 3.0)	544	5 (0.9)	(0.3, 2.1)
		Grade 4	562	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Chills ^d						
		Any	562	147 (26.2)	(22.6, 30.0)	544	67 (12.3)	(9.7, 15.4)
		Mild	562	95 (16.9)	(13.9, 20.3)	544	50 (9.2)	(6.9, 11.9)
		Moderate	562	51 (9.1)	(6.8, 11.8)	544	17 (3.1)	(1.8, 5.0)
		Severe	562	1 (0.2)	(0.0, 1.0)	544	0	(0.0, 0.7)
		Grade 4	562	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Vomiting ^e						
		Any	562	14 (2.5)	(1.4, 4.1)	544	7 (1.3)	(0.5, 2.6)
		Mild	562	13 (2.3)	(1.2, 3.9)	544	6 (1.1)	(0.4, 2.4)
		Moderate	562	0	(0.0, 0.7)	544	1 (0.2)	(0.0, 1.0)
		Severe	562	1 (0.2)	(0.0, 1.0)	544	0	(0.0, 0.7)
		Grade 4	562	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Diarrhea ^f						
		Any	562	45 (8.0)	(5.9, 10.6)	544	42 (7.7)	(5.6, 10.3)
		Mild	562	38 (6.8)	(4.8, 9.2)	544	41 (7.5)	(5.5, 10.1)
		Moderate	562	7 (1.2)	(0.5, 2.5)	544	1 (0.2)	(0.0, 1.0)
		Severe	562	0	(0.0, 0.7)	544	0	(0.0, 0.7)

Table 2. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

Sex	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
		Grade 4	562	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		New or worsened muscle pain ^d						
		Any	562	147 (26.2)	(22.6, 30.0)	544	90 (16.5)	(13.5, 19.9)
		Mild	562	63 (11.2)	(8.7, 14.1)	544	54 (9.9)	(7.5, 12.8)
		Moderate	562	84 (14.9)	(12.1, 18.2)	544	36 (6.6)	(4.7, 9.0)
		Severe	562	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Grade 4	562	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		New or worsened joint pain ^d						
		Any	562	54 (9.6)	(7.3, 12.4)	544	40 (7.4)	(5.3, 9.9)
		Mild	562	33 (5.9)	(4.1, 8.1)	544	27 (5.0)	(3.3, 7.1)
		Moderate	562	20 (3.6)	(2.2, 5.4)	544	13 (2.4)	(1.3, 4.1)
		Severe	562	1 (0.2)	(0.0, 1.0)	544	0	(0.0, 0.7)
		Grade 4	562	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Any systemic event ^g	562	439 (78.1)	(74.5, 81.5)	544	353 (64.9)	(60.7, 68.9)
		Use of antipyretic or pain medication ^h	562	217 (38.6)	(34.6, 42.8)	544	69 (12.7)	(10.0, 15.8)
	2	Fever						
		≥38.0°C	552	112 (20.3)	(17.0, 23.9)	515	1 (0.2)	(0.0, 1.1)
		≥38.0°C to 38.4°C	552	52 (9.4)	(7.1, 12.2)	515	0	(0.0, 0.7)
		>38.4°C to 38.9°C	552	45 (8.2)	(6.0, 10.8)	515	1 (0.2)	(0.0, 1.1)
		>38.9°C to 40.0°C	552	15 (2.7)	(1.5, 4.4)	515	0	(0.0, 0.7)
		>40.0°C	552	0	(0.0, 0.7)	515	0	(0.0, 0.7)
		Fatigue ^d						
		Any	552	378 (68.5)	(64.4, 72.3)	515	153 (29.7)	(25.8, 33.9)

Table 2. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

			Vaccine Group (as Administered)					
Sex	Dose	Systemic Event	BNT162b2 (30 µg)			Placebo		
			N ^a	n ^b (%)	(95% CI ^c)	N ^a	n ^b (%)	(95% CI ^c)
		Mild	552	119 (21.6)	(18.2, 25.2)	515	71 (13.8)	(10.9, 17.1)
		Moderate	552	247 (44.7)	(40.5, 49.0)	515	80 (15.5)	(12.5, 19.0)
		Severe	552	12 (2.2)	(1.1, 3.8)	515	2 (0.4)	(0.0, 1.4)
		Grade 4	552	0	(0.0, 0.7)	515	0	(0.0, 0.7)
		Headache ^d						
		Any	552	375 (67.9)	(63.9, 71.8)	515	163 (31.7)	(27.7, 35.9)
		Mild	552	154 (27.9)	(24.2, 31.8)	515	98 (19.0)	(15.7, 22.7)
		Moderate	552	206 (37.3)	(33.3, 41.5)	515	64 (12.4)	(9.7, 15.6)
		Severe	552	15 (2.7)	(1.5, 4.4)	515	1 (0.2)	(0.0, 1.1)
		Grade 4	552	0	(0.0, 0.7)	515	0	(0.0, 0.7)
		Chills ^d						
		Any	552	231 (41.8)	(37.7, 46.1)	515	48 (9.3)	(7.0, 12.2)
		Mild	552	108 (19.6)	(16.3, 23.1)	515	34 (6.6)	(4.6, 9.1)
		Moderate	552	112 (20.3)	(17.0, 23.9)	515	14 (2.7)	(1.5, 4.5)
		Severe	552	11 (2.0)	(1.0, 3.5)	515	0	(0.0, 0.7)
		Grade 4	552	0	(0.0, 0.7)	515	0	(0.0, 0.7)
		Vomiting ^e						
		Any	552	18 (3.3)	(1.9, 5.1)	515	3 (0.6)	(0.1, 1.7)
		Mild	552	16 (2.9)	(1.7, 4.7)	515	3 (0.6)	(0.1, 1.7)
		Moderate	552	2 (0.4)	(0.0, 1.3)	515	0	(0.0, 0.7)
		Severe	552	0	(0.0, 0.7)	515	0	(0.0, 0.7)
		Grade 4	552	0	(0.0, 0.7)	515	0	(0.0, 0.7)
		Diarrhea ^f						
		Any	552	34 (6.2)	(4.3, 8.5)	515	19 (3.7)	(2.2, 5.7)

Table 2. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

Sex	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
		Mild	552	29 (5.3)	(3.5, 7.5)	515	17 (3.3)	(1.9, 5.2)
		Moderate	552	5 (0.9)	(0.3, 2.1)	515	2 (0.4)	(0.0, 1.4)
		Severe	552	0	(0.0, 0.7)	515	0	(0.0, 0.7)
		Grade 4	552	0	(0.0, 0.7)	515	0	(0.0, 0.7)
		New or worsened muscle pain ^d						
		Any	552	194 (35.1)	(31.2, 39.3)	515	61 (11.8)	(9.2, 15.0)
		Mild	552	85 (15.4)	(12.5, 18.7)	515	36 (7.0)	(4.9, 9.5)
		Moderate	552	105 (19.0)	(15.8, 22.5)	515	24 (4.7)	(3.0, 6.9)
		Severe	552	4 (0.7)	(0.2, 1.8)	515	1 (0.2)	(0.0, 1.1)
		Grade 4	552	0	(0.0, 0.7)	515	0	(0.0, 0.7)
		New or worsened joint pain ^d						
		Any	552	97 (17.6)	(14.5, 21.0)	515	30 (5.8)	(4.0, 8.2)
		Mild	552	52 (9.4)	(7.1, 12.2)	515	20 (3.9)	(2.4, 5.9)
		Moderate	552	42 (7.6)	(5.5, 10.1)	515	10 (1.9)	(0.9, 3.5)
		Severe	552	3 (0.5)	(0.1, 1.6)	515	0	(0.0, 0.7)
		Grade 4	552	0	(0.0, 0.7)	515	0	(0.0, 0.7)
		Any systemic event ^g	552	464 (84.1)	(80.7, 87.0)	515	251 (48.7)	(44.3, 53.1)
		Use of antipyretic or pain medication ^h	552	297 (53.8)	(49.5, 58.0)	515	61 (11.8)	(9.2, 15.0)
	Any dose	Fever						
		≥38.0°C	564	142 (25.2)	(21.6, 29.0)	544	4 (0.7)	(0.2, 1.9)
		≥38.0°C to 38.4°C	564	72 (12.8)	(10.1, 15.8)	544	2 (0.4)	(0.0, 1.3)
		>38.4°C to 38.9°C	564	50 (8.9)	(6.7, 11.5)	544	1 (0.2)	(0.0, 1.0)
		>38.9°C to 40.0°C	564	20 (3.5)	(2.2, 5.4)	544	1 (0.2)	(0.0, 1.0)

Table 2. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

Sex	Dose	Systemic Event	Vaccine Group (as Administered)				
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)	
		>40.0°C	564	0 (0.0, 0.7)	544	0 (0.0, 0.7)	
		Fatigue ^d					
		Any	564	447 (79.3) (75.7, 82.5)	544	319 (58.6) (54.4, 62.8)	
		Mild	564	122 (21.6) (18.3, 25.3)	544	150 (27.6) (23.9, 31.5)	
		Moderate	564	306 (54.3) (50.0, 58.4)	544	164 (30.1) (26.3, 34.2)	
		Severe	564	19 (3.4) (2.0, 5.2)	544	5 (0.9) (0.3, 2.1)	
		Grade 4	564	0 (0.0, 0.7)	544	0 (0.0, 0.7)	
		Headache ^d					
		Any	564	447 (79.3) (75.7, 82.5)	544	297 (54.6) (50.3, 58.8)	
		Mild	564	165 (29.3) (25.5, 33.2)	544	171 (31.4) (27.6, 35.5)	
		Moderate	564	260 (46.1) (41.9, 50.3)	544	121 (22.2) (18.8, 26.0)	
		Severe	564	22 (3.9) (2.5, 5.8)	544	5 (0.9) (0.3, 2.1)	
		Grade 4	564	0 (0.0, 0.7)	544	0 (0.0, 0.7)	
		Chills ^d					
		Any	564	284 (50.4) (46.1, 54.6)	544	97 (17.8) (14.7, 21.3)	
		Mild	564	133 (23.6) (20.1, 27.3)	544	69 (12.7) (10.0, 15.8)	
		Moderate	564	139 (24.6) (21.1, 28.4)	544	28 (5.1) (3.4, 7.4)	
		Severe	564	12 (2.1) (1.1, 3.7)	544	0 (0.0, 0.7)	
		Grade 4	564	0 (0.0, 0.7)	544	0 (0.0, 0.7)	
		Vomiting ^e					
		Any	564	31 (5.5) (3.8, 7.7)	544	9 (1.7) (0.8, 3.1)	
		Mild	564	28 (5.0) (3.3, 7.1)	544	8 (1.5) (0.6, 2.9)	
		Moderate	564	2 (0.4) (0.0, 1.3)	544	1 (0.2) (0.0, 1.0)	
		Severe	564	1 (0.2) (0.0, 1.0)	544	0 (0.0, 0.7)	

Table 2. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

			Vaccine Group (as Administered)					
Sex	Dose	Systemic Event	BNT162b2 (30 µg)			Placebo		
			N ^a	n ^b (%)	(95% CI ^c)	N ^a	n ^b (%)	(95% CI ^c)
		Grade 4	564	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Diarrhea ^f						
		Any	564	73 (12.9)	(10.3, 16.0)	544	52 (9.6)	(7.2, 12.3)
		Mild	564	62 (11.0)	(8.5, 13.9)	544	49 (9.0)	(6.7, 11.7)
		Moderate	564	11 (2.0)	(1.0, 3.5)	544	3 (0.6)	(0.1, 1.6)
		Severe	564	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Grade 4	564	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		New or worsened muscle pain ^d						
		Any	564	257 (45.6)	(41.4, 49.8)	544	120 (22.1)	(18.6, 25.8)
		Mild	564	97 (17.2)	(14.2, 20.6)	544	67 (12.3)	(9.7, 15.4)
		Moderate	564	156 (27.7)	(24.0, 31.6)	544	52 (9.6)	(7.2, 12.3)
		Severe	564	4 (0.7)	(0.2, 1.8)	544	1 (0.2)	(0.0, 1.0)
		Grade 4	564	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		New or worsened joint pain ^d						
		Any	564	120 (21.3)	(18.0, 24.9)	544	57 (10.5)	(8.0, 13.4)
		Mild	564	64 (11.3)	(8.8, 14.3)	544	36 (6.6)	(4.7, 9.0)
		Moderate	564	52 (9.2)	(7.0, 11.9)	544	21 (3.9)	(2.4, 5.8)
		Severe	564	4 (0.7)	(0.2, 1.8)	544	0	(0.0, 0.7)
		Grade 4	564	0	(0.0, 0.7)	544	0	(0.0, 0.7)
		Any systemic event ^g	564	512 (90.8)	(88.1, 93.0)	544	397 (73.0)	(69.0, 76.7)
		Use of antipyretic or pain medication ^h	564	347 (61.5)	(57.4, 65.6)	544	112 (20.6)	(17.3, 24.2)

Table 2. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Sex – Subjects 12 Through 15 Years of Age – Safety Population

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

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

Note: Subject C4591001 1077 10771278 (13 years of age) experienced systemic events, including a temperature of 40.4°C, on the day of Dose 2. Since these events were recorded as adverse events and not in the e-diary, they do not appear in this table.

- a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.
- b. n = Number of subjects with the specified characteristic.
- c. Exact 2-sided CI based on the Clopper and Pearson method.
- d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe chills, severe muscle pain, or severe joint pain.
- e. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.
- f. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room visit or hospitalization for severe diarrhea.
- g. Any systemic event: any fever $\geq 38.0^{\circ}\text{C}$, 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 3. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Local Reaction	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)		N ^a	Placebo n ^b (%) (95% CI ^c)	
White	1	Redness ^d						
		Any	970	58 (6.0) (4.6, 7.7)		960	12 (1.3) (0.6, 2.2)	
		Mild	970	39 (4.0) (2.9, 5.5)		960	11 (1.1) (0.6, 2.0)	
		Moderate	970	18 (1.9) (1.1, 2.9)		960	1 (0.1) (0.0, 0.6)	
		Severe	970	1 (0.1) (0.0, 0.6)		960	0 (0.0, 0.4)	
		Grade 4	970	0 (0.0, 0.4)		960	0 (0.0, 0.4)	
		Swelling ^d						
		Any	970	60 (6.2) (4.8, 7.9)		960	7 (0.7) (0.3, 1.5)	
		Mild	970	42 (4.3) (3.1, 5.8)		960	6 (0.6) (0.2, 1.4)	
		Moderate	970	18 (1.9) (1.1, 2.9)		960	1 (0.1) (0.0, 0.6)	
		Severe	970	0 (0.0, 0.4)		960	0 (0.0, 0.4)	
		Grade 4	970	0 (0.0, 0.4)		960	0 (0.0, 0.4)	
		Pain at the injection site ^e						
		Any	970	838 (86.4) (84.1, 88.5)		960	221 (23.0) (20.4, 25.8)	
		Mild	970	405 (41.8) (38.6, 44.9)		960	196 (20.4) (17.9, 23.1)	
		Moderate	970	426 (43.9) (40.8, 47.1)		960	25 (2.6) (1.7, 3.8)	
		Severe	970	7 (0.7) (0.3, 1.5)		960	0 (0.0, 0.4)	
		Grade 4	970	0 (0.0, 0.4)		960	0 (0.0, 0.4)	
		Any local reaction ^f	970	842 (86.8) (84.5, 88.9)		960	229 (23.9) (21.2, 26.7)	
	2	Redness ^d						

Table 3. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Local Reaction	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)		
		Any	940	47 (5.0) (3.7, 6.6)	921	9 (1.0) (0.4, 1.8)		
		Mild	940	28 (3.0) (2.0, 4.3)	921	7 (0.8) (0.3, 1.6)		
		Moderate	940	19 (2.0) (1.2, 3.1)	921	2 (0.2) (0.0, 0.8)		
		Severe	940	0 (0.0, 0.4)	921	0 (0.0, 0.4)		
		Grade 4	940	0 (0.0, 0.4)	921	0 (0.0, 0.4)		
		Swelling ^d						
		Any	940	42 (4.5) (3.2, 6.0)	921	4 (0.4) (0.1, 1.1)		
		Mild	940	27 (2.9) (1.9, 4.2)	921	3 (0.3) (0.1, 0.9)		
		Moderate	940	15 (1.6) (0.9, 2.6)	921	1 (0.1) (0.0, 0.6)		
		Severe	940	0 (0.0, 0.4)	921	0 (0.0, 0.4)		
		Grade 4	940	0 (0.0, 0.4)	921	0 (0.0, 0.4)		
		Pain at the injection site ^e						
		Any	940	754 (80.2) (77.5, 82.7)	921	166 (18.0) (15.6, 20.7)		
		Mild	940	413 (43.9) (40.7, 47.2)	921	141 (15.3) (13.0, 17.8)		
		Moderate	940	335 (35.6) (32.6, 38.8)	921	25 (2.7) (1.8, 4.0)		
		Severe	940	6 (0.6) (0.2, 1.4)	921	0 (0.0, 0.4)		
		Grade 4	940	0 (0.0, 0.4)	921	0 (0.0, 0.4)		
		Any local reaction ^f	940	759 (80.7) (78.1, 83.2)	921	170 (18.5) (16.0, 21.1)		
	Any dose	Redness ^d						
		Any	971	85 (8.8) (7.1, 10.7)	962	17 (1.8) (1.0, 2.8)		
		Mild	971	51 (5.3) (3.9, 6.8)	962	14 (1.5) (0.8, 2.4)		
		Moderate	971	33 (3.4) (2.4, 4.7)	962	3 (0.3) (0.1, 0.9)		
		Severe	971	1 (0.1) (0.0, 0.6)	962	0 (0.0, 0.4)		
		Grade 4	971	0 (0.0, 0.4)	962	0 (0.0, 0.4)		

Table 3. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Local Reaction	Vaccine Group (as Administered)				
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)	
Black or African American	1	Swelling ^d					
		Any	971	84 (8.7) (7.0, 10.6)	962	9 (0.9) (0.4, 1.8)	
		Mild	971	56 (5.8) (4.4, 7.4)	962	7 (0.7) (0.3, 1.5)	
		Moderate	971	28 (2.9) (1.9, 4.1)	962	2 (0.2) (0.0, 0.7)	
		Severe	971	0 (0.0, 0.4)	962	0 (0.0, 0.4)	
		Grade 4	971	0 (0.0, 0.4)	962	0 (0.0, 0.4)	
		Pain at the injection site ^e					
		Any	971	884 (91.0) (89.1, 92.8)	962	284 (29.5) (26.7, 32.5)	
		Mild	971	344 (35.4) (32.4, 38.5)	962	240 (24.9) (22.2, 27.8)	
		Moderate	971	528 (54.4) (51.2, 57.5)	962	44 (4.6) (3.3, 6.1)	
		Severe	971	12 (1.2) (0.6, 2.1)	962	0 (0.0, 0.4)	
		Grade 4	971	0 (0.0, 0.4)	962	0 (0.0, 0.4)	
		Any local reaction ^f	971	888 (91.5) (89.5, 93.1)	962	292 (30.4) (27.5, 33.4)	
		Redness ^d					
		Any	50	3 (6.0) (1.3, 16.5)	57	0 (0.0, 6.3)	
		Mild	50	3 (6.0) (1.3, 16.5)	57	0 (0.0, 6.3)	
		Moderate	50	0 (0.0, 7.1)	57	0 (0.0, 6.3)	
		Severe	50	0 (0.0, 7.1)	57	0 (0.0, 6.3)	
		Grade 4	50	0 (0.0, 7.1)	57	0 (0.0, 6.3)	
		Swelling ^d					
		Any	50	8 (16.0) (7.2, 29.1)	57	3 (5.3) (1.1, 14.6)	
		Mild	50	6 (12.0) (4.5, 24.3)	57	3 (5.3) (1.1, 14.6)	
		Moderate	50	2 (4.0) (0.5, 13.7)	57	0 (0.0, 6.3)	

Table 3. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Local Reaction	Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
			N ^a	n ^b (%)	(95% CI ^c)	N ^a	n ^b (%)	(95% CI ^c)
		Severe	50	0	(0.0, 7.1)	57	0	(0.0, 6.3)
		Grade 4	50	0	(0.0, 7.1)	57	0	(0.0, 6.3)
		Pain at the injection site ^e						
		Any	50	33 (66.0)	(51.2, 78.8)	57	11 (19.3)	(10.0, 31.9)
		Mild	50	18 (36.0)	(22.9, 50.8)	57	8 (14.0)	(6.3, 25.8)
		Moderate	50	14 (28.0)	(16.2, 42.5)	57	3 (5.3)	(1.1, 14.6)
		Severe	50	1 (2.0)	(0.1, 10.6)	57	0	(0.0, 6.3)
		Grade 4	50	0	(0.0, 7.1)	57	0	(0.0, 6.3)
		Any local reaction ^f	50	33 (66.0)	(51.2, 78.8)	57	11 (19.3)	(10.0, 31.9)
	2	Redness ^d						
		Any	50	1 (2.0)	(0.1, 10.6)	52	0	(0.0, 6.8)
		Mild	50	1 (2.0)	(0.1, 10.6)	52	0	(0.0, 6.8)
		Moderate	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Severe	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Grade 4	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Swelling ^d						
		Any	50	4 (8.0)	(2.2, 19.2)	52	1 (1.9)	(0.0, 10.3)
		Mild	50	4 (8.0)	(2.2, 19.2)	52	1 (1.9)	(0.0, 10.3)
		Moderate	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Severe	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Grade 4	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Pain at the injection site ^e						
		Any	50	22 (44.0)	(30.0, 58.7)	52	7 (13.5)	(5.6, 25.8)

Table 3. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Local Reaction	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)		
		Mild	50	10 (20.0) (10.0, 33.7)	52	5 (9.6) (3.2, 21.0)		
		Moderate	50	12 (24.0) (13.1, 38.2)	52	2 (3.8) (0.5, 13.2)		
		Severe	50	0 (0.0, 7.1)	52	0 (0.0, 6.8)		
		Grade 4	50	0 (0.0, 7.1)	52	0 (0.0, 6.8)		
		Any local reaction ^f	50	23 (46.0) (31.8, 60.7)	52	7 (13.5) (5.6, 25.8)		
	Any dose	Redness ^d						
		Any	52	3 (5.8) (1.2, 15.9)	57	0 (0.0, 6.3)		
		Mild	52	3 (5.8) (1.2, 15.9)	57	0 (0.0, 6.3)		
		Moderate	52	0 (0.0, 6.8)	57	0 (0.0, 6.3)		
		Severe	52	0 (0.0, 6.8)	57	0 (0.0, 6.3)		
		Grade 4	52	0 (0.0, 6.8)	57	0 (0.0, 6.3)		
		Swelling ^d						
		Any	52	8 (15.4) (6.9, 28.1)	57	3 (5.3) (1.1, 14.6)		
		Mild	52	6 (11.5) (4.4, 23.4)	57	3 (5.3) (1.1, 14.6)		
		Moderate	52	2 (3.8) (0.5, 13.2)	57	0 (0.0, 6.3)		
		Severe	52	0 (0.0, 6.8)	57	0 (0.0, 6.3)		
		Grade 4	52	0 (0.0, 6.8)	57	0 (0.0, 6.3)		
		Pain at the injection site ^e						
		Any	52	36 (69.2) (54.9, 81.3)	57	16 (28.1) (17.0, 41.5)		
		Mild	52	14 (26.9) (15.6, 41.0)	57	12 (21.1) (11.4, 33.9)		
		Moderate	52	21 (40.4) (27.0, 54.9)	57	4 (7.0) (1.9, 17.0)		
		Severe	52	1 (1.9) (0.0, 10.3)	57	0 (0.0, 6.3)		
		Grade 4	52	0 (0.0, 6.8)	57	0 (0.0, 6.3)		

Table 3. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Local Reaction	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)		
Asian	1	Any local reaction ^f	52	36 (69.2)	(54.9, 81.3)	57	16 (28.1)	(17.0, 41.5)
		Redness ^d						
		Any	71	2 (2.8)	(0.3, 9.8)	71	0	(0.0, 5.1)
		Mild	71	1 (1.4)	(0.0, 7.6)	71	0	(0.0, 5.1)
		Moderate	71	1 (1.4)	(0.0, 7.6)	71	0	(0.0, 5.1)
		Severe	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Grade 4	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Swelling ^d						
		Any	71	7 (9.9)	(4.1, 19.3)	71	0	(0.0, 5.1)
		Mild	71	6 (8.5)	(3.2, 17.5)	71	0	(0.0, 5.1)
		Moderate	71	1 (1.4)	(0.0, 7.6)	71	0	(0.0, 5.1)
		Severe	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Grade 4	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Pain at the injection site ^e						
		Any	71	66 (93.0)	(84.3, 97.7)	71	19 (26.8)	(16.9, 38.6)
		Mild	71	27 (38.0)	(26.8, 50.3)	71	16 (22.5)	(13.5, 34.0)
		Moderate	71	37 (52.1)	(39.9, 64.1)	71	3 (4.2)	(0.9, 11.9)
		Severe	71	2 (2.8)	(0.3, 9.8)	71	0	(0.0, 5.1)
		Grade 4	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
	2	Any local reaction ^f	71	67 (94.4)	(86.2, 98.4)	71	19 (26.8)	(16.9, 38.6)
		Redness ^d						
		Any	71	6 (8.5)	(3.2, 17.5)	68	1 (1.5)	(0.0, 7.9)
		Mild	71	0	(0.0, 5.1)	68	1 (1.5)	(0.0, 7.9)

Table 3. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Local Reaction	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)		
		Moderate	71	6 (8.5) (3.2, 17.5)	68	0 (0.0, 5.3)		
		Severe	71	0 (0.0, 5.1)	68	0 (0.0, 5.3)		
		Grade 4	71	0 (0.0, 5.1)	68	0 (0.0, 5.3)		
		Swelling ^d						
		Any	71	6 (8.5) (3.2, 17.5)	68	0 (0.0, 5.3)		
		Mild	71	3 (4.2) (0.9, 11.9)	68	0 (0.0, 5.3)		
		Moderate	71	3 (4.2) (0.9, 11.9)	68	0 (0.0, 5.3)		
		Severe	71	0 (0.0, 5.1)	68	0 (0.0, 5.3)		
		Grade 4	71	0 (0.0, 5.1)	68	0 (0.0, 5.3)		
		Pain at the injection site ^e						
		Any	71	61 (85.9) (75.6, 93.0)	68	13 (19.1) (10.6, 30.5)		
		Mild	71	26 (36.6) (25.5, 48.9)	68	11 (16.2) (8.4, 27.1)		
		Moderate	71	34 (47.9) (35.9, 60.1)	68	2 (2.9) (0.4, 10.2)		
		Severe	71	1 (1.4) (0.0, 7.6)	68	0 (0.0, 5.3)		
		Grade 4	71	0 (0.0, 5.1)	68	0 (0.0, 5.3)		
		Any local reaction ^f	71	61 (85.9) (75.6, 93.0)	68	13 (19.1) (10.6, 30.5)		
	Any dose	Redness ^d						
		Any	72	7 (9.7) (4.0, 19.0)	71	1 (1.4) (0.0, 7.6)		
		Mild	72	1 (1.4) (0.0, 7.5)	71	1 (1.4) (0.0, 7.6)		
		Moderate	72	6 (8.3) (3.1, 17.3)	71	0 (0.0, 5.1)		
		Severe	72	0 (0.0, 5.0)	71	0 (0.0, 5.1)		
		Grade 4	72	0 (0.0, 5.0)	71	0 (0.0, 5.1)		
		Swelling ^d						

Table 3. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

			Vaccine Group (as Administered)						
			BNT162b2 (30 µg)			Placebo			
Race	Dose	Local Reaction	N ^a	n ^b (%)	(95% CI ^c)	N ^a	n ^b (%)	(95% CI ^c)	
	1	Any	72	9 (12.5)	(5.9, 22.4)	71	0	(0.0, 5.1)	
		Mild	72	6 (8.3)	(3.1, 17.3)	71	0	(0.0, 5.1)	
		Moderate	72	3 (4.2)	(0.9, 11.7)	71	0	(0.0, 5.1)	
		Severe	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)	
		Grade 4	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)	
		Pain at the injection site ^e							
		Any	72	68 (94.4)	(86.4, 98.5)	71	26 (36.6)	(25.5, 48.9)	
		Mild	72	22 (30.6)	(20.2, 42.5)	71	21 (29.6)	(19.3, 41.6)	
		Moderate	72	43 (59.7)	(47.5, 71.1)	71	5 (7.0)	(2.3, 15.7)	
		Severe	72	3 (4.2)	(0.9, 11.7)	71	0	(0.0, 5.1)	
		Grade 4	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)	
		Any local reaction ^f	72	69 (95.8)	(88.3, 99.1)	71	26 (36.6)	(25.5, 48.9)	
		Redness ^d							
		Any	36	2 (5.6)	(0.7, 18.7)	39	0	(0.0, 9.0)	
		Mild	36	1 (2.8)	(0.1, 14.5)	39	0	(0.0, 9.0)	
		Moderate	36	1 (2.8)	(0.1, 14.5)	39	0	(0.0, 9.0)	
		Severe	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)	
Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)			
Swelling ^d									
Any	36	3 (8.3)	(1.8, 22.5)	39	1 (2.6)	(0.1, 13.5)			
Mild	36	1 (2.8)	(0.1, 14.5)	39	0	(0.0, 9.0)			
Moderate	36	2 (5.6)	(0.7, 18.7)	39	1 (2.6)	(0.1, 13.5)			
Severe	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)			
Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)			

Table 3. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Local Reaction	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)		
	2	Pain at the injection site ^e						
		Any	36	34 (94.4)	(81.3, 99.3)	39	12 (30.8)	(17.0, 47.6)
		Mild	36	17 (47.2)	(30.4, 64.5)	39	7 (17.9)	(7.5, 33.5)
		Moderate	36	16 (44.4)	(27.9, 61.9)	39	5 (12.8)	(4.3, 27.4)
		Severe	36	1 (2.8)	(0.1, 14.5)	39	0	(0.0, 9.0)
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Any local reaction ^f	36	34 (94.4)	(81.3, 99.3)	39	12 (30.8)	(17.0, 47.6)
		Redness ^d						
		Any	36	1 (2.8)	(0.1, 14.5)	37	0	(0.0, 9.5)
		Mild	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Moderate	36	1 (2.8)	(0.1, 14.5)	37	0	(0.0, 9.5)
		Severe	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Grade 4	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Swelling ^d						
		Any	36	2 (5.6)	(0.7, 18.7)	37	1 (2.7)	(0.1, 14.2)
		Mild	36	2 (5.6)	(0.7, 18.7)	37	0	(0.0, 9.5)
		Moderate	36	0	(0.0, 9.7)	37	1 (2.7)	(0.1, 14.2)
		Severe	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Grade 4	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Pain at the injection site ^e						
		Any	36	29 (80.6)	(64.0, 91.8)	37	7 (18.9)	(8.0, 35.2)
		Mild	36	17 (47.2)	(30.4, 64.5)	37	7 (18.9)	(8.0, 35.2)
		Moderate	36	12 (33.3)	(18.6, 51.0)	37	0	(0.0, 9.5)

Table 3. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Local Reaction	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)		
		Severe	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Grade 4	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
	Any dose	Any local reaction ^f	36	29 (80.6)	(64.0, 91.8)	37	8 (21.6)	(9.8, 38.2)
		Redness ^d						
		Any	36	2 (5.6)	(0.7, 18.7)	39	0	(0.0, 9.0)
		Mild	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Moderate	36	2 (5.6)	(0.7, 18.7)	39	0	(0.0, 9.0)
		Severe	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Swelling ^d						
		Any	36	3 (8.3)	(1.8, 22.5)	39	1 (2.6)	(0.1, 13.5)
		Mild	36	1 (2.8)	(0.1, 14.5)	39	0	(0.0, 9.0)
		Moderate	36	2 (5.6)	(0.7, 18.7)	39	1 (2.6)	(0.1, 13.5)
		Severe	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Pain at the injection site ^e						
		Any	36	35 (97.2)	(85.5, 99.9)	39	15 (38.5)	(23.4, 55.4)
		Mild	36	14 (38.9)	(23.1, 56.5)	39	10 (25.6)	(13.0, 42.1)
		Moderate	36	20 (55.6)	(38.1, 72.1)	39	5 (12.8)	(4.3, 27.4)
		Severe	36	1 (2.8)	(0.1, 14.5)	39	0	(0.0, 9.0)
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Any local reaction ^f	36	35 (97.2)	(85.5, 99.9)	39	15 (38.5)	(23.4, 55.4)

Table 3. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Local Reaction	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg)		N ^a	Placebo	
				n ^b (%)	(95% CI) ^c		n ^b (%)	(95% CI) ^c

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose.

Note: Grade 4 reactions were classified by the investigator or medically qualified person.

Note: Other = American Indian or Alaska native, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.

a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.

b. n = Number of subjects with the specified characteristic.

c. Exact 2-sided CI based on the Clopper and Pearson method.

d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).

e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.

f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 05MAY2021 (23:47)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA_RR/adce_s010_lr_sev_ped_race_saf

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
White	1	Fever						
		≥38.0°C	970	92 (9.5)	(7.7, 11.5)	960	9 (0.9)	(0.4, 1.8)
		≥38.0°C to 38.4°C	970	58 (6.0)	(4.6, 7.7)	960	5 (0.5)	(0.2, 1.2)
		>38.4°C to 38.9°C	970	27 (2.8)	(1.8, 4.0)	960	2 (0.2)	(0.0, 0.8)
		>38.9°C to 40.0°C	970	6 (0.6)	(0.2, 1.3)	960	2 (0.2)	(0.0, 0.8)
		>40.0°C	970	1 (0.1)	(0.0, 0.6)	960	0	(0.0, 0.4)
		Fatigue ^d						
		Any	970	591 (60.9)	(57.8, 64.0)	960	392 (40.8)	(37.7, 44.0)
		Mild	970	243 (25.1)	(22.4, 27.9)	960	219 (22.8)	(20.2, 25.6)
		Moderate	970	337 (34.7)	(31.7, 37.8)	960	167 (17.4)	(15.0, 19.9)
		Severe	970	11 (1.1)	(0.6, 2.0)	960	6 (0.6)	(0.2, 1.4)
		Grade 4	970	0	(0.0, 0.4)	960	0	(0.0, 0.4)
		Headache ^d						
		Any	970	539 (55.6)	(52.4, 58.7)	960	349 (36.4)	(33.3, 39.5)
		Mild	970	315 (32.5)	(29.5, 35.5)	960	229 (23.9)	(21.2, 26.7)
		Moderate	970	216 (22.3)	(19.7, 25.0)	960	112 (11.7)	(9.7, 13.9)
		Severe	970	8 (0.8)	(0.4, 1.6)	960	8 (0.8)	(0.4, 1.6)
		Grade 4	970	0	(0.0, 0.4)	960	0	(0.0, 0.4)
		Chills ^d						
		Any	970	261 (26.9)	(24.1, 29.8)	960	86 (9.0)	(7.2, 10.9)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)		N ^a	Placebo n ^b (%) (95% CI ^c)	
		Mild	970	160 (16.5)	(14.2, 19.0)	960	67 (7.0)	(5.4, 8.8)
		Moderate	970	96 (9.9)	(8.1, 12.0)	960	18 (1.9)	(1.1, 2.9)
		Severe	970	5 (0.5)	(0.2, 1.2)	960	1 (0.1)	(0.0, 0.6)
		Grade 4	970	0	(0.0, 0.4)	960	0	(0.0, 0.4)
		Vomiting ^e						
		Any	970	22 (2.3)	(1.4, 3.4)	960	6 (0.6)	(0.2, 1.4)
		Mild	970	22 (2.3)	(1.4, 3.4)	960	4 (0.4)	(0.1, 1.1)
		Moderate	970	0	(0.0, 0.4)	960	2 (0.2)	(0.0, 0.8)
		Severe	970	0	(0.0, 0.4)	960	0	(0.0, 0.4)
		Grade 4	970	0	(0.0, 0.4)	960	0	(0.0, 0.4)
		Diarrhea ^f						
		Any	970	80 (8.2)	(6.6, 10.2)	960	72 (7.5)	(5.9, 9.4)
		Mild	970	69 (7.1)	(5.6, 8.9)	960	63 (6.6)	(5.1, 8.3)
		Moderate	970	11 (1.1)	(0.6, 2.0)	960	9 (0.9)	(0.4, 1.8)
		Severe	970	0	(0.0, 0.4)	960	0	(0.0, 0.4)
		Grade 4	970	0	(0.0, 0.4)	960	0	(0.0, 0.4)
		New or worsened muscle pain ^d						
		Any	970	235 (24.2)	(21.6, 27.1)	960	124 (12.9)	(10.9, 15.2)
		Mild	970	104 (10.7)	(8.8, 12.8)	960	74 (7.7)	(6.1, 9.6)
		Moderate	970	129 (13.3)	(11.2, 15.6)	960	50 (5.2)	(3.9, 6.8)
		Severe	970	2 (0.2)	(0.0, 0.7)	960	0	(0.0, 0.4)
		Grade 4	970	0	(0.0, 0.4)	960	0	(0.0, 0.4)
		New or worsened joint pain ^d						
		Any	970	89 (9.2)	(7.4, 11.2)	960	69 (7.2)	(5.6, 9.0)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI) ^c		N ^a	Placebo n ^b (%) (95% CI) ^c	
		Mild	970	54 (5.6)	(4.2, 7.2)	960	45 (4.7)	(3.4, 6.2)
		Moderate	970	34 (3.5)	(2.4, 4.9)	960	24 (2.5)	(1.6, 3.7)
		Severe	970	1 (0.1)	(0.0, 0.6)	960	0	(0.0, 0.4)
		Grade 4	970	0	(0.0, 0.4)	960	0	(0.0, 0.4)
		Any systemic event ^g	970	760 (78.4)	(75.6, 80.9)	960	551 (57.4)	(54.2, 60.5)
		Use of antipyretic or pain medication ^h	970	354 (36.5)	(33.5, 39.6)	960	91 (9.5)	(7.7, 11.5)
	2	Fever						
		≥38.0°C	940	189 (20.1)	(17.6, 22.8)	921	6 (0.7)	(0.2, 1.4)
		≥38.0°C to 38.4°C	940	98 (10.4)	(8.5, 12.6)	921	4 (0.4)	(0.1, 1.1)
		>38.4°C to 38.9°C	940	69 (7.3)	(5.8, 9.2)	921	1 (0.1)	(0.0, 0.6)
		>38.9°C to 40.0°C	940	22 (2.3)	(1.5, 3.5)	921	1 (0.1)	(0.0, 0.6)
		>40.0°C	940	0	(0.0, 0.4)	921	0	(0.0, 0.4)
		Fatigue ^d						
		Any	940	635 (67.6)	(64.5, 70.5)	921	221 (24.0)	(21.3, 26.9)
		Mild	940	204 (21.7)	(19.1, 24.5)	921	112 (12.2)	(10.1, 14.4)
		Moderate	940	406 (43.2)	(40.0, 46.4)	921	105 (11.4)	(9.4, 13.6)
		Severe	940	25 (2.7)	(1.7, 3.9)	921	4 (0.4)	(0.1, 1.1)
		Grade 4	940	0	(0.0, 0.4)	921	0	(0.0, 0.4)
		Headache ^d						
		Any	940	621 (66.1)	(62.9, 69.1)	921	227 (24.6)	(21.9, 27.6)
		Mild	940	262 (27.9)	(25.0, 30.9)	921	146 (15.9)	(13.6, 18.4)
		Moderate	940	340 (36.2)	(33.1, 39.3)	921	80 (8.7)	(6.9, 10.7)
		Severe	940	19 (2.0)	(1.2, 3.1)	921	1 (0.1)	(0.0, 0.6)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
		Grade 4	940	0	(0.0, 0.4)	921	0	(0.0, 0.4)
		Chills ^d						
		Any	940	401 (42.7)	(39.5, 45.9)	921	62 (6.7)	(5.2, 8.5)
		Mild	940	193 (20.5)	(18.0, 23.3)	921	45 (4.9)	(3.6, 6.5)
		Moderate	940	190 (20.2)	(17.7, 22.9)	921	17 (1.8)	(1.1, 2.9)
		Severe	940	18 (1.9)	(1.1, 3.0)	921	0	(0.0, 0.4)
		Grade 4	940	0	(0.0, 0.4)	921	0	(0.0, 0.4)
		Vomiting ^e						
		Any	940	27 (2.9)	(1.9, 4.2)	921	10 (1.1)	(0.5, 2.0)
		Mild	940	24 (2.6)	(1.6, 3.8)	921	9 (1.0)	(0.4, 1.8)
		Moderate	940	3 (0.3)	(0.1, 0.9)	921	1 (0.1)	(0.0, 0.6)
		Severe	940	0	(0.0, 0.4)	921	0	(0.0, 0.4)
		Grade 4	940	0	(0.0, 0.4)	921	0	(0.0, 0.4)
		Diarrhea ^f						
		Any	940	58 (6.2)	(4.7, 7.9)	921	39 (4.2)	(3.0, 5.7)
		Mild	940	53 (5.6)	(4.3, 7.3)	921	35 (3.8)	(2.7, 5.2)
		Moderate	940	5 (0.5)	(0.2, 1.2)	921	4 (0.4)	(0.1, 1.1)
		Severe	940	0	(0.0, 0.4)	921	0	(0.0, 0.4)
		Grade 4	940	0	(0.0, 0.4)	921	0	(0.0, 0.4)
		New or worsened muscle pain ^d						
		Any	940	310 (33.0)	(30.0, 36.1)	921	74 (8.0)	(6.4, 10.0)
		Mild	940	128 (13.6)	(11.5, 16.0)	921	39 (4.2)	(3.0, 5.7)
		Moderate	940	176 (18.7)	(16.3, 21.4)	921	33 (3.6)	(2.5, 5.0)
		Severe	940	6 (0.6)	(0.2, 1.4)	921	2 (0.2)	(0.0, 0.8)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)		N ^a	Placebo n ^b (%) (95% CI ^c)	
		Grade 4	940	0	(0.0, 0.4)	921	0	(0.0, 0.4)
		New or worsened joint pain ^d						
		Any	940	159 (16.9)	(14.6, 19.5)	921	46 (5.0)	(3.7, 6.6)
		Mild	940	85 (9.0)	(7.3, 11.1)	921	29 (3.1)	(2.1, 4.5)
		Moderate	940	70 (7.4)	(5.9, 9.3)	921	17 (1.8)	(1.1, 2.9)
		Severe	940	4 (0.4)	(0.1, 1.1)	921	0	(0.0, 0.4)
		Grade 4	940	0	(0.0, 0.4)	921	0	(0.0, 0.4)
		Any systemic event ^g	940	784 (83.4)	(80.9, 85.7)	921	377 (40.9)	(37.7, 44.2)
		Use of antipyretic or pain medication ^h	940	484 (51.5)	(48.2, 54.7)	921	89 (9.7)	(7.8, 11.8)
	Any dose	Fever						
		≥38.0°C	971	236 (24.3)	(21.6, 27.1)	962	14 (1.5)	(0.8, 2.4)
		≥38.0°C to 38.4°C	971	122 (12.6)	(10.5, 14.8)	962	8 (0.8)	(0.4, 1.6)
		>38.4°C to 38.9°C	971	86 (8.9)	(7.1, 10.8)	962	3 (0.3)	(0.1, 0.9)
		>38.9°C to 40.0°C	971	27 (2.8)	(1.8, 4.0)	962	3 (0.3)	(0.1, 0.9)
		>40.0°C	971	1 (0.1)	(0.0, 0.6)	962	0	(0.0, 0.4)
		Fatigue ^d						
		Any	971	765 (78.8)	(76.1, 81.3)	962	459 (47.7)	(44.5, 50.9)
		Mild	971	211 (21.7)	(19.2, 24.5)	962	234 (24.3)	(21.6, 27.2)
		Moderate	971	519 (53.5)	(50.3, 56.6)	962	215 (22.3)	(19.8, 25.1)
		Severe	971	35 (3.6)	(2.5, 5.0)	962	10 (1.0)	(0.5, 1.9)
		Grade 4	971	0	(0.0, 0.4)	962	0	(0.0, 0.4)
		Headache ^d						
		Any	971	741 (76.3)	(73.5, 79.0)	962	441 (45.8)	(42.7, 49.1)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
		Mild	971	277 (28.5)	(25.7, 31.5)	962	268 (27.9)	(25.0, 30.8)
		Moderate	971	439 (45.2)	(42.0, 48.4)	962	165 (17.2)	(14.8, 19.7)
		Severe	971	25 (2.6)	(1.7, 3.8)	962	8 (0.8)	(0.4, 1.6)
		Grade 4	971	0	(0.0, 0.4)	962	0	(0.0, 0.4)
		Chills ^d						
		Any	971	484 (49.8)	(46.7, 53.0)	962	129 (13.4)	(11.3, 15.7)
		Mild	971	217 (22.3)	(19.8, 25.1)	962	96 (10.0)	(8.2, 12.0)
		Moderate	971	245 (25.2)	(22.5, 28.1)	962	32 (3.3)	(2.3, 4.7)
		Severe	971	22 (2.3)	(1.4, 3.4)	962	1 (0.1)	(0.0, 0.6)
		Grade 4	971	0	(0.0, 0.4)	962	0	(0.0, 0.4)
		Vomiting ^e						
		Any	971	48 (4.9)	(3.7, 6.5)	962	15 (1.6)	(0.9, 2.6)
		Mild	971	45 (4.6)	(3.4, 6.2)	962	12 (1.2)	(0.6, 2.2)
		Moderate	971	3 (0.3)	(0.1, 0.9)	962	3 (0.3)	(0.1, 0.9)
		Severe	971	0	(0.0, 0.4)	962	0	(0.0, 0.4)
		Grade 4	971	0	(0.0, 0.4)	962	0	(0.0, 0.4)
		Diarrhea ^f						
		Any	971	125 (12.9)	(10.8, 15.1)	962	94 (9.8)	(8.0, 11.8)
		Mild	971	110 (11.3)	(9.4, 13.5)	962	81 (8.4)	(6.7, 10.4)
		Moderate	971	15 (1.5)	(0.9, 2.5)	962	13 (1.4)	(0.7, 2.3)
		Severe	971	0	(0.0, 0.4)	962	0	(0.0, 0.4)
		Grade 4	971	0	(0.0, 0.4)	962	0	(0.0, 0.4)
		New or worsened muscle pain ^d						
		Any	971	415 (42.7)	(39.6, 45.9)	962	162 (16.8)	(14.5, 19.4)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)		N ^a	Placebo n ^b (%) (95% CI ^c)	
Black or African American	1	Mild	971	156 (16.1)	(13.8, 18.5)	962	89 (9.3)	(7.5, 11.3)
		Moderate	971	251 (25.8)	(23.1, 28.7)	962	71 (7.4)	(5.8, 9.2)
		Severe	971	8 (0.8)	(0.4, 1.6)	962	2 (0.2)	(0.0, 0.7)
		Grade 4	971	0	(0.0, 0.4)	962	0	(0.0, 0.4)
		New or worsened joint pain ^d						
		Any	971	203 (20.9)	(18.4, 23.6)	962	95 (9.9)	(8.1, 11.9)
		Mild	971	109 (11.2)	(9.3, 13.4)	962	57 (5.9)	(4.5, 7.6)
		Moderate	971	89 (9.2)	(7.4, 11.2)	962	38 (4.0)	(2.8, 5.4)
		Severe	971	5 (0.5)	(0.2, 1.2)	962	0	(0.0, 0.4)
		Grade 4	971	0	(0.0, 0.4)	962	0	(0.0, 0.4)
		Any systemic event ^g	971	889 (91.6)	(89.6, 93.2)	962	628 (65.3)	(62.2, 68.3)
		Use of antipyretic or pain medication ^h	971	575 (59.2)	(56.1, 62.3)	962	152 (15.8)	(13.6, 18.3)
		Fever						
		≥38.0°C	50	5 (10.0)	(3.3, 21.8)	57	1 (1.8)	(0.0, 9.4)
		≥38.0°C to 38.4°C	50	3 (6.0)	(1.3, 16.5)	57	1 (1.8)	(0.0, 9.4)
		>38.4°C to 38.9°C	50	1 (2.0)	(0.1, 10.6)	57	0	(0.0, 6.3)
		>38.9°C to 40.0°C	50	1 (2.0)	(0.1, 10.6)	57	0	(0.0, 6.3)
		>40.0°C	50	0	(0.0, 7.1)	57	0	(0.0, 6.3)
		Fatigue ^d						
		Any	50	18 (36.0)	(22.9, 50.8)	57	10 (17.5)	(8.7, 29.9)
		Mild	50	6 (12.0)	(4.5, 24.3)	57	7 (12.3)	(5.1, 23.7)
		Moderate	50	10 (20.0)	(10.0, 33.7)	57	2 (3.5)	(0.4, 12.1)
		Severe	50	2 (4.0)	(0.5, 13.7)	57	1 (1.8)	(0.0, 9.4)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)		
		Grade 4	50	0	(0.0, 7.1)	57	0	(0.0, 6.3)
		Headache ^d						
		Any	50	21 (42.0)	(28.2, 56.8)	57	8 (14.0)	(6.3, 25.8)
		Mild	50	11 (22.0)	(11.5, 36.0)	57	5 (8.8)	(2.9, 19.3)
		Moderate	50	9 (18.0)	(8.6, 31.4)	57	3 (5.3)	(1.1, 14.6)
		Severe	50	1 (2.0)	(0.1, 10.6)	57	0	(0.0, 6.3)
		Grade 4	50	0	(0.0, 7.1)	57	0	(0.0, 6.3)
		Chills ^d						
		Any	50	12 (24.0)	(13.1, 38.2)	57	7 (12.3)	(5.1, 23.7)
		Mild	50	9 (18.0)	(8.6, 31.4)	57	3 (5.3)	(1.1, 14.6)
		Moderate	50	3 (6.0)	(1.3, 16.5)	57	3 (5.3)	(1.1, 14.6)
		Severe	50	0	(0.0, 7.1)	57	1 (1.8)	(0.0, 9.4)
		Grade 4	50	0	(0.0, 7.1)	57	0	(0.0, 6.3)
		Vomiting ^e						
		Any	50	4 (8.0)	(2.2, 19.2)	57	1 (1.8)	(0.0, 9.4)
		Mild	50	4 (8.0)	(2.2, 19.2)	57	1 (1.8)	(0.0, 9.4)
		Moderate	50	0	(0.0, 7.1)	57	0	(0.0, 6.3)
		Severe	50	0	(0.0, 7.1)	57	0	(0.0, 6.3)
		Grade 4	50	0	(0.0, 7.1)	57	0	(0.0, 6.3)
		Diarrhea ^f						
		Any	50	1 (2.0)	(0.1, 10.6)	57	1 (1.8)	(0.0, 9.4)
		Mild	50	1 (2.0)	(0.1, 10.6)	57	0	(0.0, 6.3)
		Moderate	50	0	(0.0, 7.1)	57	1 (1.8)	(0.0, 9.4)
		Severe	50	0	(0.0, 7.1)	57	0	(0.0, 6.3)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)		N ^a	Placebo n ^b (%) (95% CI ^c)	
		Grade 4	50	0	(0.0, 7.1)	57	0	(0.0, 6.3)
		New or worsened muscle pain ^d						
		Any	50	10 (20.0)	(10.0, 33.7)	57	4 (7.0)	(1.9, 17.0)
		Mild	50	6 (12.0)	(4.5, 24.3)	57	1 (1.8)	(0.0, 9.4)
		Moderate	50	4 (8.0)	(2.2, 19.2)	57	3 (5.3)	(1.1, 14.6)
		Severe	50	0	(0.0, 7.1)	57	0	(0.0, 6.3)
		Grade 4	50	0	(0.0, 7.1)	57	0	(0.0, 6.3)
		New or worsened joint pain ^d						
		Any	50	5 (10.0)	(3.3, 21.8)	57	2 (3.5)	(0.4, 12.1)
		Mild	50	3 (6.0)	(1.3, 16.5)	57	1 (1.8)	(0.0, 9.4)
		Moderate	50	2 (4.0)	(0.5, 13.7)	57	1 (1.8)	(0.0, 9.4)
		Severe	50	0	(0.0, 7.1)	57	0	(0.0, 6.3)
		Grade 4	50	0	(0.0, 7.1)	57	0	(0.0, 6.3)
		Any systemic event ^g	50	29 (58.0)	(43.2, 71.8)	57	18 (31.6)	(19.9, 45.2)
		Use of antipyretic or pain medication ^h	50	11 (22.0)	(11.5, 36.0)	57	3 (5.3)	(1.1, 14.6)
	2	Fever						
		≥38.0°C	50	3 (6.0)	(1.3, 16.5)	52	1 (1.9)	(0.0, 10.3)
		≥38.0°C to 38.4°C	50	2 (4.0)	(0.5, 13.7)	52	1 (1.9)	(0.0, 10.3)
		>38.4°C to 38.9°C	50	1 (2.0)	(0.1, 10.6)	52	0	(0.0, 6.8)
		>38.9°C to 40.0°C	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		>40.0°C	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Fatigue ^d						
		Any	50	17 (34.0)	(21.2, 48.8)	52	8 (15.4)	(6.9, 28.1)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
		Mild	50	7 (14.0)	(5.8, 26.7)	52	2 (3.8)	(0.5, 13.2)
		Moderate	50	10 (20.0)	(10.0, 33.7)	52	6 (11.5)	(4.4, 23.4)
		Severe	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Grade 4	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Headache ^d						
		Any	50	17 (34.0)	(21.2, 48.8)	52	6 (11.5)	(4.4, 23.4)
		Mild	50	6 (12.0)	(4.5, 24.3)	52	2 (3.8)	(0.5, 13.2)
		Moderate	50	11 (22.0)	(11.5, 36.0)	52	4 (7.7)	(2.1, 18.5)
		Severe	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Grade 4	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Chills ^d						
		Any	50	9 (18.0)	(8.6, 31.4)	52	3 (5.8)	(1.2, 15.9)
		Mild	50	6 (12.0)	(4.5, 24.3)	52	0	(0.0, 6.8)
		Moderate	50	3 (6.0)	(1.3, 16.5)	52	3 (5.8)	(1.2, 15.9)
		Severe	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Grade 4	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Vomiting ^e						
		Any	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Mild	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Moderate	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Severe	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Grade 4	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Diarrhea ^f						
		Any	50	2 (4.0)	(0.5, 13.7)	52	0	(0.0, 6.8)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)		N ^a	Placebo n ^b (%) (95% CI ^c)	
		Mild	50	1 (2.0)	(0.1, 10.6)	52	0	(0.0, 6.8)
		Moderate	50	1 (2.0)	(0.1, 10.6)	52	0	(0.0, 6.8)
		Severe	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Grade 4	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		New or worsened muscle pain ^d						
		Any	50	7 (14.0)	(5.8, 26.7)	52	3 (5.8)	(1.2, 15.9)
		Mild	50	4 (8.0)	(2.2, 19.2)	52	1 (1.9)	(0.0, 10.3)
		Moderate	50	3 (6.0)	(1.3, 16.5)	52	2 (3.8)	(0.5, 13.2)
		Severe	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Grade 4	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		New or worsened joint pain ^d						
		Any	50	2 (4.0)	(0.5, 13.7)	52	0	(0.0, 6.8)
		Mild	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Moderate	50	2 (4.0)	(0.5, 13.7)	52	0	(0.0, 6.8)
		Severe	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Grade 4	50	0	(0.0, 7.1)	52	0	(0.0, 6.8)
		Any systemic event ^g	50	23 (46.0)	(31.8, 60.7)	52	14 (26.9)	(15.6, 41.0)
		Use of antipyretic or pain medication ^h	50	17 (34.0)	(21.2, 48.8)	52	3 (5.8)	(1.2, 15.9)
	Any dose	Fever						
		≥38.0°C	52	8 (15.4)	(6.9, 28.1)	57	1 (1.8)	(0.0, 9.4)
		≥38.0°C to 38.4°C	52	5 (9.6)	(3.2, 21.0)	57	1 (1.8)	(0.0, 9.4)
		>38.4°C to 38.9°C	52	2 (3.8)	(0.5, 13.2)	57	0	(0.0, 6.3)
		>38.9°C to 40.0°C	52	1 (1.9)	(0.0, 10.3)	57	0	(0.0, 6.3)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI) ^c		N ^a	Placebo n ^b (%) (95% CI) ^c	
		>40.0°C	52	0	(0.0, 6.8)	57	0	(0.0, 6.3)
		Fatigue ^d						
		Any	52	25 (48.1)	(34.0, 62.4)	57	15 (26.3)	(15.5, 39.7)
		Mild	52	8 (15.4)	(6.9, 28.1)	57	6 (10.5)	(4.0, 21.5)
		Moderate	52	15 (28.8)	(17.1, 43.1)	57	8 (14.0)	(6.3, 25.8)
		Severe	52	2 (3.8)	(0.5, 13.2)	57	1 (1.8)	(0.0, 9.4)
		Grade 4	52	0	(0.0, 6.8)	57	0	(0.0, 6.3)
		Headache ^d						
		Any	52	29 (55.8)	(41.3, 69.5)	57	13 (22.8)	(12.7, 35.8)
		Mild	52	11 (21.2)	(11.1, 34.7)	57	6 (10.5)	(4.0, 21.5)
		Moderate	52	17 (32.7)	(20.3, 47.1)	57	7 (12.3)	(5.1, 23.7)
		Severe	52	1 (1.9)	(0.0, 10.3)	57	0	(0.0, 6.3)
		Grade 4	52	0	(0.0, 6.8)	57	0	(0.0, 6.3)
		Chills ^d						
		Any	52	18 (34.6)	(22.0, 49.1)	57	9 (15.8)	(7.5, 27.9)
		Mild	52	12 (23.1)	(12.5, 36.8)	57	2 (3.5)	(0.4, 12.1)
		Moderate	52	6 (11.5)	(4.4, 23.4)	57	6 (10.5)	(4.0, 21.5)
		Severe	52	0	(0.0, 6.8)	57	1 (1.8)	(0.0, 9.4)
		Grade 4	52	0	(0.0, 6.8)	57	0	(0.0, 6.3)
		Vomiting ^e						
		Any	52	4 (7.7)	(2.1, 18.5)	57	1 (1.8)	(0.0, 9.4)
		Mild	52	4 (7.7)	(2.1, 18.5)	57	1 (1.8)	(0.0, 9.4)
		Moderate	52	0	(0.0, 6.8)	57	0	(0.0, 6.3)
		Severe	52	0	(0.0, 6.8)	57	0	(0.0, 6.3)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI) ^c		N ^a	Placebo n ^b (%) (95% CI) ^c	
Asian	1	Grade 4	52	0	(0.0, 6.8)	57	0	(0.0, 6.3)
		Diarrhea ^f						
		Any	52	2 (3.8)	(0.5, 13.2)	57	1 (1.8)	(0.0, 9.4)
		Mild	52	1 (1.9)	(0.0, 10.3)	57	0	(0.0, 6.3)
		Moderate	52	1 (1.9)	(0.0, 10.3)	57	1 (1.8)	(0.0, 9.4)
		Severe	52	0	(0.0, 6.8)	57	0	(0.0, 6.3)
		Grade 4	52	0	(0.0, 6.8)	57	0	(0.0, 6.3)
		New or worsened muscle pain ^d						
		Any	52	15 (28.8)	(17.1, 43.1)	57	6 (10.5)	(4.0, 21.5)
		Mild	52	9 (17.3)	(8.2, 30.3)	57	1 (1.8)	(0.0, 9.4)
		Moderate	52	6 (11.5)	(4.4, 23.4)	57	5 (8.8)	(2.9, 19.3)
		Severe	52	0	(0.0, 6.8)	57	0	(0.0, 6.3)
		Grade 4	52	0	(0.0, 6.8)	57	0	(0.0, 6.3)
		New or worsened joint pain ^d						
		Any	52	7 (13.5)	(5.6, 25.8)	57	2 (3.5)	(0.4, 12.1)
		Mild	52	3 (5.8)	(1.2, 15.9)	57	1 (1.8)	(0.0, 9.4)
		Moderate	52	4 (7.7)	(2.1, 18.5)	57	1 (1.8)	(0.0, 9.4)
		Severe	52	0	(0.0, 6.8)	57	0	(0.0, 6.3)
		Grade 4	52	0	(0.0, 6.8)	57	0	(0.0, 6.3)
		Any systemic event ^g	52	35 (67.3)	(52.9, 79.7)	57	23 (40.4)	(27.6, 54.2)
		Use of antipyretic or pain medication ^h	52	23 (44.2)	(30.5, 58.7)	57	6 (10.5)	(4.0, 21.5)
		Fever						
		≥38.0°C	71	13 (18.3)	(10.1, 29.3)	71	2 (2.8)	(0.3, 9.8)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)		N ^a	Placebo n ^b (%) (95% CI ^c)	
		≥38.0°C to 38.4°C	71	10 (14.1)	(7.0, 24.4)	71	2 (2.8)	(0.3, 9.8)
		>38.4°C to 38.9°C	71	1 (1.4)	(0.0, 7.6)	71	0	(0.0, 5.1)
		>38.9°C to 40.0°C	71	2 (2.8)	(0.3, 9.8)	71	0	(0.0, 5.1)
		>40.0°C	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Fatigue ^d						
		Any	71	49 (69.0)	(56.9, 79.5)	71	34 (47.9)	(35.9, 60.1)
		Mild	71	19 (26.8)	(16.9, 38.6)	71	15 (21.1)	(12.3, 32.4)
		Moderate	71	29 (40.8)	(29.3, 53.2)	71	18 (25.4)	(15.8, 37.1)
		Severe	71	1 (1.4)	(0.0, 7.6)	71	1 (1.4)	(0.0, 7.6)
		Grade 4	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Headache ^d						
		Any	71	39 (54.9)	(42.7, 66.8)	71	24 (33.8)	(23.0, 46.0)
		Mild	71	19 (26.8)	(16.9, 38.6)	71	11 (15.5)	(8.0, 26.0)
		Moderate	71	19 (26.8)	(16.9, 38.6)	71	12 (16.9)	(9.0, 27.7)
		Severe	71	1 (1.4)	(0.0, 7.6)	71	1 (1.4)	(0.0, 7.6)
		Grade 4	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Chills ^d						
		Any	71	27 (38.0)	(26.8, 50.3)	71	11 (15.5)	(8.0, 26.0)
		Mild	71	18 (25.4)	(15.8, 37.1)	71	8 (11.3)	(5.0, 21.0)
		Moderate	71	9 (12.7)	(6.0, 22.7)	71	3 (4.2)	(0.9, 11.9)
		Severe	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Grade 4	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Vomiting ^e						
		Any	71	3 (4.2)	(0.9, 11.9)	71	3 (4.2)	(0.9, 11.9)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
		Mild	71	3 (4.2)	(0.9, 11.9)	71	3 (4.2)	(0.9, 11.9)
		Moderate	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Severe	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Grade 4	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Diarrhea ^f						
		Any	71	6 (8.5)	(3.2, 17.5)	71	7 (9.9)	(4.1, 19.3)
		Mild	71	6 (8.5)	(3.2, 17.5)	71	7 (9.9)	(4.1, 19.3)
		Moderate	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Severe	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Grade 4	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		New or worsened muscle pain ^d						
		Any	71	21 (29.6)	(19.3, 41.6)	71	12 (16.9)	(9.0, 27.7)
		Mild	71	13 (18.3)	(10.1, 29.3)	71	8 (11.3)	(5.0, 21.0)
		Moderate	71	8 (11.3)	(5.0, 21.0)	71	4 (5.6)	(1.6, 13.8)
		Severe	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Grade 4	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		New or worsened joint pain ^d						
		Any	71	9 (12.7)	(6.0, 22.7)	71	5 (7.0)	(2.3, 15.7)
		Mild	71	5 (7.0)	(2.3, 15.7)	71	4 (5.6)	(1.6, 13.8)
		Moderate	71	4 (5.6)	(1.6, 13.8)	71	1 (1.4)	(0.0, 7.6)
		Severe	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Grade 4	71	0	(0.0, 5.1)	71	0	(0.0, 5.1)
		Any systemic event ^g	71	60 (84.5)	(74.0, 92.0)	71	42 (59.2)	(46.8, 70.7)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
	2	Use of antipyretic or pain medication ^h	71	33 (46.5)	(34.5, 58.7)	71	10 (14.1)	(7.0, 24.4)
		Fever						
		≥38.0°C	71	19 (26.8)	(16.9, 38.6)	68	0	(0.0, 5.3)
		≥38.0°C to 38.4°C	71	5 (7.0)	(2.3, 15.7)	68	0	(0.0, 5.3)
		>38.4°C to 38.9°C	71	11 (15.5)	(8.0, 26.0)	68	0	(0.0, 5.3)
		>38.9°C to 40.0°C	71	3 (4.2)	(0.9, 11.9)	68	0	(0.0, 5.3)
		>40.0°C	71	0	(0.0, 5.1)	68	0	(0.0, 5.3)
		Fatigue ^d						
		Any	71	50 (70.4)	(58.4, 80.7)	68	21 (30.9)	(20.2, 43.3)
		Mild	71	13 (18.3)	(10.1, 29.3)	68	12 (17.6)	(9.5, 28.8)
		Moderate	71	36 (50.7)	(38.6, 62.8)	68	9 (13.2)	(6.2, 23.6)
		Severe	71	1 (1.4)	(0.0, 7.6)	68	0	(0.0, 5.3)
		Grade 4	71	0	(0.0, 5.1)	68	0	(0.0, 5.3)
		Headache ^d						
		Any	71	49 (69.0)	(56.9, 79.5)	68	21 (30.9)	(20.2, 43.3)
		Mild	71	23 (32.4)	(21.8, 44.5)	68	15 (22.1)	(12.9, 33.8)
		Moderate	71	24 (33.8)	(23.0, 46.0)	68	6 (8.8)	(3.3, 18.2)
		Severe	71	2 (2.8)	(0.3, 9.8)	68	0	(0.0, 5.3)
		Grade 4	71	0	(0.0, 5.1)	68	0	(0.0, 5.3)
		Chills ^d						
		Any	71	33 (46.5)	(34.5, 58.7)	68	6 (8.8)	(3.3, 18.2)
		Mild	71	13 (18.3)	(10.1, 29.3)	68	6 (8.8)	(3.3, 18.2)
		Moderate	71	18 (25.4)	(15.8, 37.1)	68	0	(0.0, 5.3)
		Severe	71	2 (2.8)	(0.3, 9.8)	68	0	(0.0, 5.3)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)		N ^a	Placebo n ^b (%) (95% CI ^c)	
		Grade 4	71	0	(0.0, 5.1)	68	0	(0.0, 5.3)
		Vomiting ^e						
		Any	71	0	(0.0, 5.1)	68	2 (2.9)	(0.4, 10.2)
		Mild	71	0	(0.0, 5.1)	68	2 (2.9)	(0.4, 10.2)
		Moderate	71	0	(0.0, 5.1)	68	0	(0.0, 5.3)
		Severe	71	0	(0.0, 5.1)	68	0	(0.0, 5.3)
		Grade 4	71	0	(0.0, 5.1)	68	0	(0.0, 5.3)
		Diarrhea ^f						
		Any	71	4 (5.6)	(1.6, 13.8)	68	2 (2.9)	(0.4, 10.2)
		Mild	71	4 (5.6)	(1.6, 13.8)	68	2 (2.9)	(0.4, 10.2)
		Moderate	71	0	(0.0, 5.1)	68	0	(0.0, 5.3)
		Severe	71	0	(0.0, 5.1)	68	0	(0.0, 5.3)
		Grade 4	71	0	(0.0, 5.1)	68	0	(0.0, 5.3)
		New or worsened muscle pain ^d						
		Any	71	22 (31.0)	(20.5, 43.1)	68	10 (14.7)	(7.3, 25.4)
		Mild	71	11 (15.5)	(8.0, 26.0)	68	8 (11.8)	(5.2, 21.9)
		Moderate	71	11 (15.5)	(8.0, 26.0)	68	2 (2.9)	(0.4, 10.2)
		Severe	71	0	(0.0, 5.1)	68	0	(0.0, 5.3)
		Grade 4	71	0	(0.0, 5.1)	68	0	(0.0, 5.3)
		New or worsened joint pain ^d						
		Any	71	8 (11.3)	(5.0, 21.0)	68	5 (7.4)	(2.4, 16.3)
		Mild	71	3 (4.2)	(0.9, 11.9)	68	1 (1.5)	(0.0, 7.9)
		Moderate	71	5 (7.0)	(2.3, 15.7)	68	4 (5.9)	(1.6, 14.4)
		Severe	71	0	(0.0, 5.1)	68	0	(0.0, 5.3)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
		Grade 4	71	0	(0.0, 5.1)	68	0	(0.0, 5.3)
		Any systemic event ^g	71	66 (93.0)	(84.3, 97.7)	68	30 (44.1)	(32.1, 56.7)
		Use of antipyretic or pain medication ^h	71	44 (62.0)	(49.7, 73.2)	68	3 (4.4)	(0.9, 12.4)
	Any dose	Fever						
		≥38.0°C	72	24 (33.3)	(22.7, 45.4)	71	2 (2.8)	(0.3, 9.8)
		≥38.0°C to 38.4°C	72	10 (13.9)	(6.9, 24.1)	71	2 (2.8)	(0.3, 9.8)
		>38.4°C to 38.9°C	72	10 (13.9)	(6.9, 24.1)	71	0	(0.0, 5.1)
		>38.9°C to 40.0°C	72	4 (5.6)	(1.5, 13.6)	71	0	(0.0, 5.1)
		>40.0°C	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)
		Fatigue ^d						
		Any	72	60 (83.3)	(72.7, 91.1)	71	40 (56.3)	(44.0, 68.1)
		Mild	72	12 (16.7)	(8.9, 27.3)	71	15 (21.1)	(12.3, 32.4)
		Moderate	72	46 (63.9)	(51.7, 74.9)	71	24 (33.8)	(23.0, 46.0)
		Severe	72	2 (2.8)	(0.3, 9.7)	71	1 (1.4)	(0.0, 7.6)
		Grade 4	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)
		Headache ^d						
		Any	72	55 (76.4)	(64.9, 85.6)	71	33 (46.5)	(34.5, 58.7)
		Mild	72	22 (30.6)	(20.2, 42.5)	71	16 (22.5)	(13.5, 34.0)
		Moderate	72	30 (41.7)	(30.2, 53.9)	71	16 (22.5)	(13.5, 34.0)
		Severe	72	3 (4.2)	(0.9, 11.7)	71	1 (1.4)	(0.0, 7.6)
		Grade 4	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)
		Chills ^d						
		Any	72	40 (55.6)	(43.4, 67.3)	71	14 (19.7)	(11.2, 30.9)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)		N ^a	Placebo n ^b (%) (95% CI ^c)	
		Mild	72	18 (25.0)	(15.5, 36.6)	71	11 (15.5)	(8.0, 26.0)
		Moderate	72	20 (27.8)	(17.9, 39.6)	71	3 (4.2)	(0.9, 11.9)
		Severe	72	2 (2.8)	(0.3, 9.7)	71	0	(0.0, 5.1)
		Grade 4	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)
		Vomiting ^e						
		Any	72	3 (4.2)	(0.9, 11.7)	71	5 (7.0)	(2.3, 15.7)
		Mild	72	3 (4.2)	(0.9, 11.7)	71	5 (7.0)	(2.3, 15.7)
		Moderate	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)
		Severe	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)
		Grade 4	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)
		Diarrhea ^f						
		Any	72	10 (13.9)	(6.9, 24.1)	71	7 (9.9)	(4.1, 19.3)
		Mild	72	10 (13.9)	(6.9, 24.1)	71	7 (9.9)	(4.1, 19.3)
		Moderate	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)
		Severe	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)
		Grade 4	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)
		New or worsened muscle pain ^d						
		Any	72	31 (43.1)	(31.4, 55.3)	71	20 (28.2)	(18.1, 40.1)
		Mild	72	15 (20.8)	(12.2, 32.0)	71	15 (21.1)	(12.3, 32.4)
		Moderate	72	16 (22.2)	(13.3, 33.6)	71	5 (7.0)	(2.3, 15.7)
		Severe	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)
		Grade 4	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)
		New or worsened joint pain ^d						
		Any	72	12 (16.7)	(8.9, 27.3)	71	9 (12.7)	(6.0, 22.7)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)		N ^a	Placebo n ^b (%) (95% CI ^c)	
Other	1	Mild	72	6 (8.3)	(3.1, 17.3)	71	5 (7.0)	(2.3, 15.7)
		Moderate	72	6 (8.3)	(3.1, 17.3)	71	4 (5.6)	(1.6, 13.8)
		Severe	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)
		Grade 4	72	0	(0.0, 5.0)	71	0	(0.0, 5.1)
		Any systemic event ^g	72	69 (95.8)	(88.3, 99.1)	71	47 (66.2)	(54.0, 77.0)
		Use of antipyretic or pain medication ^h	72	49 (68.1)	(56.0, 78.6)	71	11 (15.5)	(8.0, 26.0)
		Fever						
		≥38.0°C	36	4 (11.1)	(3.1, 26.1)	39	0	(0.0, 9.0)
		≥38.0°C to 38.4°C	36	3 (8.3)	(1.8, 22.5)	39	0	(0.0, 9.0)
		>38.4°C to 38.9°C	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		>38.9°C to 40.0°C	36	1 (2.8)	(0.1, 14.5)	39	0	(0.0, 9.0)
		>40.0°C	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Fatigue ^d						
		Any	36	19 (52.8)	(35.5, 69.6)	39	21 (53.8)	(37.2, 69.9)
		Mild	36	10 (27.8)	(14.2, 45.2)	39	9 (23.1)	(11.1, 39.3)
		Moderate	36	8 (22.2)	(10.1, 39.2)	39	12 (30.8)	(17.0, 47.6)
		Severe	36	1 (2.8)	(0.1, 14.5)	39	0	(0.0, 9.0)
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Headache ^d						
		Any	36	24 (66.7)	(49.0, 81.4)	39	15 (38.5)	(23.4, 55.4)
		Mild	36	16 (44.4)	(27.9, 61.9)	39	11 (28.2)	(15.0, 44.9)
		Moderate	36	7 (19.4)	(8.2, 36.0)	39	4 (10.3)	(2.9, 24.2)
		Severe	36	1 (2.8)	(0.1, 14.5)	39	0	(0.0, 9.0)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)		
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Chills ^d						
		Any	36	11 (30.6)	(16.3, 48.1)	39	5 (12.8)	(4.3, 27.4)
		Mild	36	8 (22.2)	(10.1, 39.2)	39	4 (10.3)	(2.9, 24.2)
		Moderate	36	3 (8.3)	(1.8, 22.5)	39	1 (2.6)	(0.1, 13.5)
		Severe	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Vomiting ^e						
		Any	36	2 (5.6)	(0.7, 18.7)	39	0	(0.0, 9.0)
		Mild	36	1 (2.8)	(0.1, 14.5)	39	0	(0.0, 9.0)
		Moderate	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Severe	36	1 (2.8)	(0.1, 14.5)	39	0	(0.0, 9.0)
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Diarrhea ^f						
		Any	36	3 (8.3)	(1.8, 22.5)	39	2 (5.1)	(0.6, 17.3)
		Mild	36	1 (2.8)	(0.1, 14.5)	39	2 (5.1)	(0.6, 17.3)
		Moderate	36	2 (5.6)	(0.7, 18.7)	39	0	(0.0, 9.0)
		Severe	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		New or worsened muscle pain ^d						
		Any	36	6 (16.7)	(6.4, 32.8)	39	8 (20.5)	(9.3, 36.5)
		Mild	36	2 (5.6)	(0.7, 18.7)	39	5 (12.8)	(4.3, 27.4)
		Moderate	36	4 (11.1)	(3.1, 26.1)	39	3 (7.7)	(1.6, 20.9)
		Severe	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)		
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		New or worsened joint pain ^d						
		Any	36	6 (16.7)	(6.4, 32.8)	39	1 (2.6)	(0.1, 13.5)
		Mild	36	4 (11.1)	(3.1, 26.1)	39	0	(0.0, 9.0)
		Moderate	36	2 (5.6)	(0.7, 18.7)	39	1 (2.6)	(0.1, 13.5)
		Severe	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Any systemic event ^g	36	28 (77.8)	(60.8, 89.9)	39	25 (64.1)	(47.2, 78.8)
		Use of antipyretic or pain medication ^h	36	15 (41.7)	(25.5, 59.2)	39	7 (17.9)	(7.5, 33.5)
	2	Fever						
		≥38.0°C	36	4 (11.1)	(3.1, 26.1)	37	0	(0.0, 9.5)
		≥38.0°C to 38.4°C	36	2 (5.6)	(0.7, 18.7)	37	0	(0.0, 9.5)
		>38.4°C to 38.9°C	36	2 (5.6)	(0.7, 18.7)	37	0	(0.0, 9.5)
		>38.9°C to 40.0°C	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		>40.0°C	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Fatigue ^d						
		Any	36	24 (66.7)	(49.0, 81.4)	37	14 (37.8)	(22.5, 55.2)
		Mild	36	8 (22.2)	(10.1, 39.2)	37	7 (18.9)	(8.0, 35.2)
		Moderate	36	16 (44.4)	(27.9, 61.9)	37	7 (18.9)	(8.0, 35.2)
		Severe	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Grade 4	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Headache ^d						
		Any	36	21 (58.3)	(40.8, 74.5)	37	9 (24.3)	(11.8, 41.2)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)		N ^a	Placebo n ^b (%) (95% CI ^c)	
		Mild	36	11 (30.6)	(16.3, 48.1)	37	6 (16.2)	(6.2, 32.0)
		Moderate	36	9 (25.0)	(12.1, 42.2)	37	3 (8.1)	(1.7, 21.9)
		Severe	36	1 (2.8)	(0.1, 14.5)	37	0	(0.0, 9.5)
		Grade 4	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Chills ^d						
		Any	36	12 (33.3)	(18.6, 51.0)	37	2 (5.4)	(0.7, 18.2)
		Mild	36	9 (25.0)	(12.1, 42.2)	37	1 (2.7)	(0.1, 14.2)
		Moderate	36	3 (8.3)	(1.8, 22.5)	37	1 (2.7)	(0.1, 14.2)
		Severe	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Grade 4	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Vomiting ^e						
		Any	36	2 (5.6)	(0.7, 18.7)	37	0	(0.0, 9.5)
		Mild	36	1 (2.8)	(0.1, 14.5)	37	0	(0.0, 9.5)
		Moderate	36	1 (2.8)	(0.1, 14.5)	37	0	(0.0, 9.5)
		Severe	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Grade 4	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Diarrhea ^f						
		Any	36	1 (2.8)	(0.1, 14.5)	37	2 (5.4)	(0.7, 18.2)
		Mild	36	1 (2.8)	(0.1, 14.5)	37	1 (2.7)	(0.1, 14.2)
		Moderate	36	0	(0.0, 9.7)	37	1 (2.7)	(0.1, 14.2)
		Severe	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Grade 4	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		New or worsened muscle pain ^d						
		Any	36	16 (44.4)	(27.9, 61.9)	37	3 (8.1)	(1.7, 21.9)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)		N ^a	Placebo n ^b (%) (95% CI ^c)	
		Mild	36	9 (25.0)	(12.1, 42.2)	37	3 (8.1)	(1.7, 21.9)
		Moderate	36	7 (19.4)	(8.2, 36.0)	37	0	(0.0, 9.5)
		Severe	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Grade 4	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		New or worsened joint pain ^d						
		Any	36	4 (11.1)	(3.1, 26.1)	37	0	(0.0, 9.5)
		Mild	36	3 (8.3)	(1.8, 22.5)	37	0	(0.0, 9.5)
		Moderate	36	1 (2.8)	(0.1, 14.5)	37	0	(0.0, 9.5)
		Severe	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Grade 4	36	0	(0.0, 9.7)	37	0	(0.0, 9.5)
		Any systemic event ^g	36	31 (86.1)	(70.5, 95.3)	37	18 (48.6)	(31.9, 65.6)
		Use of antipyretic or pain medication ^h	36	12 (33.3)	(18.6, 51.0)	37	0	(0.0, 9.5)
	Any dose	Fever						
		≥38.0°C	36	7 (19.4)	(8.2, 36.0)	39	0	(0.0, 9.0)
		≥38.0°C to 38.4°C	36	4 (11.1)	(3.1, 26.1)	39	0	(0.0, 9.0)
		>38.4°C to 38.9°C	36	2 (5.6)	(0.7, 18.7)	39	0	(0.0, 9.0)
		>38.9°C to 40.0°C	36	1 (2.8)	(0.1, 14.5)	39	0	(0.0, 9.0)
		>40.0°C	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Fatigue ^d						
		Any	36	26 (72.2)	(54.8, 85.8)	39	24 (61.5)	(44.6, 76.6)
		Mild	36	8 (22.2)	(10.1, 39.2)	39	11 (28.2)	(15.0, 44.9)
		Moderate	36	17 (47.2)	(30.4, 64.5)	39	13 (33.3)	(19.1, 50.2)
		Severe	36	1 (2.8)	(0.1, 14.5)	39	0	(0.0, 9.0)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)		N ^a	Placebo n ^b (%) (95% CI ^c)	
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Headache ^d						
		Any	36	29 (80.6)	(64.0, 91.8)	39	19 (48.7)	(32.4, 65.2)
		Mild	36	14 (38.9)	(23.1, 56.5)	39	13 (33.3)	(19.1, 50.2)
		Moderate	36	13 (36.1)	(20.8, 53.8)	39	6 (15.4)	(5.9, 30.5)
		Severe	36	2 (5.6)	(0.7, 18.7)	39	0	(0.0, 9.0)
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Chills ^d						
		Any	36	15 (41.7)	(25.5, 59.2)	39	7 (17.9)	(7.5, 33.5)
		Mild	36	10 (27.8)	(14.2, 45.2)	39	5 (12.8)	(4.3, 27.4)
		Moderate	36	5 (13.9)	(4.7, 29.5)	39	2 (5.1)	(0.6, 17.3)
		Severe	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Vomiting ^e						
		Any	36	4 (11.1)	(3.1, 26.1)	39	0	(0.0, 9.0)
		Mild	36	2 (5.6)	(0.7, 18.7)	39	0	(0.0, 9.0)
		Moderate	36	1 (2.8)	(0.1, 14.5)	39	0	(0.0, 9.0)
		Severe	36	1 (2.8)	(0.1, 14.5)	39	0	(0.0, 9.0)
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Diarrhea ^f						
		Any	36	4 (11.1)	(3.1, 26.1)	39	4 (10.3)	(2.9, 24.2)
		Mild	36	2 (5.6)	(0.7, 18.7)	39	3 (7.7)	(1.6, 20.9)
		Moderate	36	2 (5.6)	(0.7, 18.7)	39	1 (2.6)	(0.1, 13.5)
		Severe	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

Race	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)		N ^a	Placebo n ^b (%) (95% CI ^c)	
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		New or worsened muscle pain ^d						
		Any	36	16 (44.4)	(27.9, 61.9)	39	8 (20.5)	(9.3, 36.5)
		Mild	36	7 (19.4)	(8.2, 36.0)	39	5 (12.8)	(4.3, 27.4)
		Moderate	36	9 (25.0)	(12.1, 42.2)	39	3 (7.7)	(1.6, 20.9)
		Severe	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		New or worsened joint pain ^d						
		Any	36	7 (19.4)	(8.2, 36.0)	39	1 (2.6)	(0.1, 13.5)
		Mild	36	4 (11.1)	(3.1, 26.1)	39	0	(0.0, 9.0)
		Moderate	36	3 (8.3)	(1.8, 22.5)	39	1 (2.6)	(0.1, 13.5)
		Severe	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Grade 4	36	0	(0.0, 9.7)	39	0	(0.0, 9.0)
		Any systemic event ^g	36	33 (91.7)	(77.5, 98.2)	39	28 (71.8)	(55.1, 85.0)
		Use of antipyretic or pain medication ^h	36	17 (47.2)	(30.4, 64.5)	39	7 (17.9)	(7.5, 33.5)

Table 4. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Race – Subjects 12 Through 15 Years of Age – Safety Population

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

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

Note: Subject C4591001 1077 10771278 (13 years of age) experienced systemic events, including a temperature of 40.4°C, on the day of Dose 2. Since these events were recorded as adverse events and not in the e-diary, they do not appear in this table.

Note: Other = American Indian or Alaska native, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.

a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.

b. n = Number of subjects with the specified characteristic.

c. Exact 2-sided CI based on the Clopper and Pearson method.

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

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

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

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

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

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 06MAY2021 (00:45)

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Table 5. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Local Reaction	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)		N ^a	Placebo n ^b (%) (95% CI ^c)	
Hispanic/Latino	1	Redness ^d						
		Any	132	7 (5.3) (2.2, 10.6)		130	1 (0.8) (0.0, 4.2)	
		Mild	132	5 (3.8) (1.2, 8.6)		130	1 (0.8) (0.0, 4.2)	
		Moderate	132	1 (0.8) (0.0, 4.1)		130	0 (0.0, 2.8)	
		Severe	132	1 (0.8) (0.0, 4.1)		130	0 (0.0, 2.8)	
		Grade 4	132	0 (0.0, 2.8)		130	0 (0.0, 2.8)	
		Swelling ^d						
		Any	132	12 (9.1) (4.8, 15.3)		130	6 (4.6) (1.7, 9.8)	
		Mild	132	8 (6.1) (2.7, 11.6)		130	4 (3.1) (0.8, 7.7)	
		Moderate	132	4 (3.0) (0.8, 7.6)		130	2 (1.5) (0.2, 5.4)	
		Severe	132	0 (0.0, 2.8)		130	0 (0.0, 2.8)	
		Grade 4	132	0 (0.0, 2.8)		130	0 (0.0, 2.8)	
		Pain at the injection site ^e						
		Any	132	108 (81.8) (74.2, 88.0)		130	30 (23.1) (16.1, 31.3)	
		Mild	132	45 (34.1) (26.1, 42.8)		130	22 (16.9) (10.9, 24.5)	
		Moderate	132	61 (46.2) (37.5, 55.1)		130	8 (6.2) (2.7, 11.8)	
		Severe	132	2 (1.5) (0.2, 5.4)		130	0 (0.0, 2.8)	
		Grade 4	132	0 (0.0, 2.8)		130	0 (0.0, 2.8)	
		Any local reaction ^f	132	108 (81.8) (74.2, 88.0)		130	32 (24.6) (17.5, 32.9)	
	2	Redness ^d						

Table 5. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Local Reaction	Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
			N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
		Any	128	3 (2.3)	(0.5, 6.7)	124	0	(0.0, 2.9)
		Mild	128	2 (1.6)	(0.2, 5.5)	124	0	(0.0, 2.9)
		Moderate	128	1 (0.8)	(0.0, 4.3)	124	0	(0.0, 2.9)
		Severe	128	0	(0.0, 2.8)	124	0	(0.0, 2.9)
		Grade 4	128	0	(0.0, 2.8)	124	0	(0.0, 2.9)
		Swelling ^d						
		Any	128	8 (6.3)	(2.7, 11.9)	124	3 (2.4)	(0.5, 6.9)
		Mild	128	8 (6.3)	(2.7, 11.9)	124	1 (0.8)	(0.0, 4.4)
		Moderate	128	0	(0.0, 2.8)	124	2 (1.6)	(0.2, 5.7)
		Severe	128	0	(0.0, 2.8)	124	0	(0.0, 2.9)
		Grade 4	128	0	(0.0, 2.8)	124	0	(0.0, 2.9)
		Pain at the injection site ^e						
		Any	128	99 (77.3)	(69.1, 84.3)	124	20 (16.1)	(10.1, 23.8)
		Mild	128	59 (46.1)	(37.2, 55.1)	124	17 (13.7)	(8.2, 21.0)
		Moderate	128	38 (29.7)	(21.9, 38.4)	124	3 (2.4)	(0.5, 6.9)
		Severe	128	2 (1.6)	(0.2, 5.5)	124	0	(0.0, 2.9)
		Grade 4	128	0	(0.0, 2.8)	124	0	(0.0, 2.9)
		Any local reaction ^f	128	101 (78.9)	(70.8, 85.6)	124	22 (17.7)	(11.5, 25.6)
	Any dose	Redness ^d						
		Any	132	8 (6.1)	(2.7, 11.6)	130	1 (0.8)	(0.0, 4.2)
		Mild	132	5 (3.8)	(1.2, 8.6)	130	1 (0.8)	(0.0, 4.2)
		Moderate	132	2 (1.5)	(0.2, 5.4)	130	0	(0.0, 2.8)
		Severe	132	1 (0.8)	(0.0, 4.1)	130	0	(0.0, 2.8)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)

Table 5. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Local Reaction	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)		
Non-Hispanic/non-Latino	1	Swelling ^d						
		Any	132	15 (11.4)	(6.5, 18.0)	130	6 (4.6)	(1.7, 9.8)
		Mild	132	11 (8.3)	(4.2, 14.4)	130	3 (2.3)	(0.5, 6.6)
		Moderate	132	4 (3.0)	(0.8, 7.6)	130	3 (2.3)	(0.5, 6.6)
		Severe	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Pain at the injection site ^e						
		Any	132	118 (89.4)	(82.8, 94.1)	130	39 (30.0)	(22.3, 38.7)
		Mild	132	46 (34.8)	(26.8, 43.6)	130	29 (22.3)	(15.5, 30.4)
		Moderate	132	68 (51.5)	(42.7, 60.3)	130	10 (7.7)	(3.8, 13.7)
		Severe	132	4 (3.0)	(0.8, 7.6)	130	0	(0.0, 2.8)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Any local reaction ^f	132	118 (89.4)	(82.8, 94.1)	130	41 (31.5)	(23.7, 40.3)
		Redness ^d						
		Any	993	58 (5.8)	(4.5, 7.5)	994	11 (1.1)	(0.6, 2.0)
		Mild	993	39 (3.9)	(2.8, 5.3)	994	10 (1.0)	(0.5, 1.8)
		Moderate	993	19 (1.9)	(1.2, 3.0)	994	1 (0.1)	(0.0, 0.6)
		Severe	993	0	(0.0, 0.4)	994	0	(0.0, 0.4)
		Grade 4	993	0	(0.0, 0.4)	994	0	(0.0, 0.4)
		Swelling ^d						
		Any	993	65 (6.5)	(5.1, 8.3)	994	5 (0.5)	(0.2, 1.2)
		Mild	993	47 (4.7)	(3.5, 6.2)	994	5 (0.5)	(0.2, 1.2)
		Moderate	993	18 (1.8)	(1.1, 2.8)	994	0	(0.0, 0.4)

Table 5. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Local Reaction	Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
			N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
		Severe	993	0	(0.0, 0.4)	994	0	(0.0, 0.4)
		Grade 4	993	0	(0.0, 0.4)	994	0	(0.0, 0.4)
		Pain at the injection site ^e						
		Any	993	861 (86.7)	(84.4, 88.8)	994	233 (23.4)	(20.8, 26.2)
		Mild	993	421 (42.4)	(39.3, 45.5)	994	205 (20.6)	(18.1, 23.3)
		Moderate	993	431 (43.4)	(40.3, 46.6)	994	28 (2.8)	(1.9, 4.0)
		Severe	993	9 (0.9)	(0.4, 1.7)	994	0	(0.0, 0.4)
		Grade 4	993	0	(0.0, 0.4)	994	0	(0.0, 0.4)
		Any local reaction ^f	993	866 (87.2)	(85.0, 89.2)	994	239 (24.0)	(21.4, 26.8)
	2	Redness ^d						
		Any	967	52 (5.4)	(4.0, 7.0)	951	10 (1.1)	(0.5, 1.9)
		Mild	967	27 (2.8)	(1.8, 4.0)	951	8 (0.8)	(0.4, 1.7)
		Moderate	967	25 (2.6)	(1.7, 3.8)	951	2 (0.2)	(0.0, 0.8)
		Severe	967	0	(0.0, 0.4)	951	0	(0.0, 0.4)
		Grade 4	967	0	(0.0, 0.4)	951	0	(0.0, 0.4)
		Swelling ^d						
		Any	967	45 (4.7)	(3.4, 6.2)	951	3 (0.3)	(0.1, 0.9)
		Mild	967	27 (2.8)	(1.8, 4.0)	951	3 (0.3)	(0.1, 0.9)
		Moderate	967	18 (1.9)	(1.1, 2.9)	951	0	(0.0, 0.4)
		Severe	967	0	(0.0, 0.4)	951	0	(0.0, 0.4)
		Grade 4	967	0	(0.0, 0.4)	951	0	(0.0, 0.4)
		Pain at the injection site ^e						
		Any	967	765 (79.1)	(76.4, 81.6)	951	173 (18.2)	(15.8, 20.8)

Table 5. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Local Reaction	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)		
		Mild	967	405 (41.9)	(38.7, 45.1)	951	147 (15.5)	(13.2, 17.9)
		Moderate	967	355 (36.7)	(33.7, 39.8)	951	26 (2.7)	(1.8, 4.0)
		Severe	967	5 (0.5)	(0.2, 1.2)	951	0	(0.0, 0.4)
		Grade 4	967	0	(0.0, 0.4)	951	0	(0.0, 0.4)
		Any local reaction ^f	967	769 (79.5)	(76.8, 82.0)	951	176 (18.5)	(16.1, 21.1)
	Any dose	Redness ^d						
		Any	997	89 (8.9)	(7.2, 10.9)	996	17 (1.7)	(1.0, 2.7)
		Mild	997	50 (5.0)	(3.7, 6.6)	996	14 (1.4)	(0.8, 2.3)
		Moderate	997	39 (3.9)	(2.8, 5.3)	996	3 (0.3)	(0.1, 0.9)
		Severe	997	0	(0.0, 0.4)	996	0	(0.0, 0.4)
		Grade 4	997	0	(0.0, 0.4)	996	0	(0.0, 0.4)
		Swelling ^d						
		Any	997	88 (8.8)	(7.1, 10.8)	996	7 (0.7)	(0.3, 1.4)
		Mild	997	58 (5.8)	(4.4, 7.5)	996	7 (0.7)	(0.3, 1.4)
		Moderate	997	30 (3.0)	(2.0, 4.3)	996	0	(0.0, 0.4)
		Severe	997	0	(0.0, 0.4)	996	0	(0.0, 0.4)
		Grade 4	997	0	(0.0, 0.4)	996	0	(0.0, 0.4)
		Pain at the injection site ^e						
		Any	997	903 (90.6)	(88.6, 92.3)	996	302 (30.3)	(27.5, 33.3)
		Mild	997	347 (34.8)	(31.8, 37.9)	996	254 (25.5)	(22.8, 28.3)
		Moderate	997	543 (54.5)	(51.3, 57.6)	996	48 (4.8)	(3.6, 6.3)
		Severe	997	13 (1.3)	(0.7, 2.2)	996	0	(0.0, 0.4)
		Grade 4	997	0	(0.0, 0.4)	996	0	(0.0, 0.4)

Table 5. Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Local Reaction	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)		N ^a	Placebo n ^b (%) (95% CI ^c)	
		Any local reaction ^f	997	908 (91.1) (89.1, 92.8)		996	308 (30.9) (28.1, 33.9)	

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose.

Note: Grade 4 reactions were classified by the investigator or medically qualified person.

a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.

b. n = Number of subjects with the specified characteristic.

c. Exact 2-sided CI based on the Clopper and Pearson method.

d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).

e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.

f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 05MAY2021 (23:47)

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Table 6. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Systemic Event	Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
			N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
Hispanic/Latino	1	Fever						
		≥38.0°C	132	17 (12.9)	(7.7, 19.8)	130	3 (2.3)	(0.5, 6.6)
		≥38.0°C to 38.4°C	132	13 (9.8)	(5.3, 16.3)	130	2 (1.5)	(0.2, 5.4)
		>38.4°C to 38.9°C	132	2 (1.5)	(0.2, 5.4)	130	1 (0.8)	(0.0, 4.2)
		>38.9°C to 40.0°C	132	2 (1.5)	(0.2, 5.4)	130	0	(0.0, 2.8)
		>40.0°C	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Fatigue ^d						
		Any	132	78 (59.1)	(50.2, 67.6)	130	53 (40.8)	(32.2, 49.7)
		Mild	132	34 (25.8)	(18.5, 34.1)	130	31 (23.8)	(16.8, 32.1)
		Moderate	132	43 (32.6)	(24.7, 41.3)	130	21 (16.2)	(10.3, 23.6)
		Severe	132	1 (0.8)	(0.0, 4.1)	130	1 (0.8)	(0.0, 4.2)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Headache ^d						
		Any	132	71 (53.8)	(44.9, 62.5)	130	41 (31.5)	(23.7, 40.3)
		Mild	132	41 (31.1)	(23.3, 39.7)	130	32 (24.6)	(17.5, 32.9)
		Moderate	132	30 (22.7)	(15.9, 30.8)	130	8 (6.2)	(2.7, 11.8)
		Severe	132	0	(0.0, 2.8)	130	1 (0.8)	(0.0, 4.2)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Chills ^d						
		Any	132	30 (22.7)	(15.9, 30.8)	130	16 (12.3)	(7.2, 19.2)
		Mild	132	24 (18.2)	(12.0, 25.8)	130	12 (9.2)	(4.9, 15.6)
		Moderate	132	5 (3.8)	(1.2, 8.6)	130	2 (1.5)	(0.2, 5.4)

Table 6. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
		Severe	132	1 (0.8)	(0.0, 4.1)	130	2 (1.5)	(0.2, 5.4)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Vomiting ^e						
		Any	132	1 (0.8)	(0.0, 4.1)	130	1 (0.8)	(0.0, 4.2)
		Mild	132	1 (0.8)	(0.0, 4.1)	130	1 (0.8)	(0.0, 4.2)
		Moderate	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Severe	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Diarrhea ^f						
		Any	132	10 (7.6)	(3.7, 13.5)	130	8 (6.2)	(2.7, 11.8)
		Mild	132	8 (6.1)	(2.7, 11.6)	130	7 (5.4)	(2.2, 10.8)
		Moderate	132	2 (1.5)	(0.2, 5.4)	130	1 (0.8)	(0.0, 4.2)
		Severe	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		New or worsened muscle pain ^d						
		Any	132	28 (21.2)	(14.6, 29.2)	130	12 (9.2)	(4.9, 15.6)
		Mild	132	15 (11.4)	(6.5, 18.0)	130	8 (6.2)	(2.7, 11.8)
		Moderate	132	13 (9.8)	(5.3, 16.3)	130	4 (3.1)	(0.8, 7.7)
		Severe	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		New or worsened joint pain ^d						
		Any	132	9 (6.8)	(3.2, 12.5)	130	6 (4.6)	(1.7, 9.8)
		Mild	132	5 (3.8)	(1.2, 8.6)	130	4 (3.1)	(0.8, 7.7)
		Moderate	132	4 (3.0)	(0.8, 7.6)	130	2 (1.5)	(0.2, 5.4)

Table 6. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
		Severe	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Any systemic event ^g	132	98 (74.2)	(65.9, 81.5)	130	72 (55.4)	(46.4, 64.1)
		Use of antipyretic or pain medication ^h	132	49 (37.1)	(28.9, 46.0)	130	8 (6.2)	(2.7, 11.8)
	2	Fever						
		≥38.0°C	128	12 (9.4)	(4.9, 15.8)	124	2 (1.6)	(0.2, 5.7)
		≥38.0°C to 38.4°C	128	6 (4.7)	(1.7, 9.9)	124	2 (1.6)	(0.2, 5.7)
		>38.4°C to 38.9°C	128	5 (3.9)	(1.3, 8.9)	124	0	(0.0, 2.9)
		>38.9°C to 40.0°C	128	1 (0.8)	(0.0, 4.3)	124	0	(0.0, 2.9)
		>40.0°C	128	0	(0.0, 2.8)	124	0	(0.0, 2.9)
		Fatigue ^d						
		Any	128	76 (59.4)	(50.3, 68.0)	124	28 (22.6)	(15.6, 31.0)
		Mild	128	25 (19.5)	(13.1, 27.5)	124	15 (12.1)	(6.9, 19.2)
		Moderate	128	47 (36.7)	(28.4, 45.7)	124	13 (10.5)	(5.7, 17.3)
		Severe	128	4 (3.1)	(0.9, 7.8)	124	0	(0.0, 2.9)
		Grade 4	128	0	(0.0, 2.8)	124	0	(0.0, 2.9)
		Headache ^d						
		Any	128	66 (51.6)	(42.6, 60.5)	124	26 (21.0)	(14.2, 29.2)
		Mild	128	29 (22.7)	(15.7, 30.9)	124	19 (15.3)	(9.5, 22.9)
		Moderate	128	36 (28.1)	(20.5, 36.8)	124	7 (5.6)	(2.3, 11.3)
		Severe	128	1 (0.8)	(0.0, 4.3)	124	0	(0.0, 2.9)
		Grade 4	128	0	(0.0, 2.8)	124	0	(0.0, 2.9)
		Chills ^d						

Table 6. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
		Any	128	37 (28.9)	(21.2, 37.6)	124	10 (8.1)	(3.9, 14.3)
		Mild	128	19 (14.8)	(9.2, 22.2)	124	6 (4.8)	(1.8, 10.2)
		Moderate	128	14 (10.9)	(6.1, 17.7)	124	4 (3.2)	(0.9, 8.1)
		Severe	128	4 (3.1)	(0.9, 7.8)	124	0	(0.0, 2.9)
		Grade 4	128	0	(0.0, 2.8)	124	0	(0.0, 2.9)
		Vomiting ^e						
		Any	128	1 (0.8)	(0.0, 4.3)	124	3 (2.4)	(0.5, 6.9)
		Mild	128	1 (0.8)	(0.0, 4.3)	124	3 (2.4)	(0.5, 6.9)
		Moderate	128	0	(0.0, 2.8)	124	0	(0.0, 2.9)
		Severe	128	0	(0.0, 2.8)	124	0	(0.0, 2.9)
		Grade 4	128	0	(0.0, 2.8)	124	0	(0.0, 2.9)
		Diarrhea ^f						
		Any	128	12 (9.4)	(4.9, 15.8)	124	5 (4.0)	(1.3, 9.2)
		Mild	128	10 (7.8)	(3.8, 13.9)	124	4 (3.2)	(0.9, 8.1)
		Moderate	128	2 (1.6)	(0.2, 5.5)	124	1 (0.8)	(0.0, 4.4)
		Severe	128	0	(0.0, 2.8)	124	0	(0.0, 2.9)
		Grade 4	128	0	(0.0, 2.8)	124	0	(0.0, 2.9)
		New or worsened muscle pain ^d						
		Any	128	41 (32.0)	(24.1, 40.9)	124	6 (4.8)	(1.8, 10.2)
		Mild	128	17 (13.3)	(7.9, 20.4)	124	3 (2.4)	(0.5, 6.9)
		Moderate	128	22 (17.2)	(11.1, 24.9)	124	3 (2.4)	(0.5, 6.9)
		Severe	128	2 (1.6)	(0.2, 5.5)	124	0	(0.0, 2.9)
		Grade 4	128	0	(0.0, 2.8)	124	0	(0.0, 2.9)
		New or worsened joint pain ^d						

Table 6. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
		Any	128	18 (14.1)	(8.6, 21.3)	124	2 (1.6)	(0.2, 5.7)
		Mild	128	9 (7.0)	(3.3, 12.9)	124	1 (0.8)	(0.0, 4.4)
		Moderate	128	7 (5.5)	(2.2, 10.9)	124	1 (0.8)	(0.0, 4.4)
		Severe	128	2 (1.6)	(0.2, 5.5)	124	0	(0.0, 2.9)
		Grade 4	128	0	(0.0, 2.8)	124	0	(0.0, 2.9)
		Any systemic event ^g	128	95 (74.2)	(65.7, 81.5)	124	49 (39.5)	(30.9, 48.7)
		Use of antipyretic or pain medication ^h	128	55 (43.0)	(34.3, 52.0)	124	9 (7.3)	(3.4, 13.3)
	Any dose	Fever						
		≥38.0°C	132	25 (18.9)	(12.6, 26.7)	130	4 (3.1)	(0.8, 7.7)
		≥38.0°C to 38.4°C	132	16 (12.1)	(7.1, 18.9)	130	3 (2.3)	(0.5, 6.6)
		>38.4°C to 38.9°C	132	6 (4.5)	(1.7, 9.6)	130	1 (0.8)	(0.0, 4.2)
		>38.9°C to 40.0°C	132	3 (2.3)	(0.5, 6.5)	130	0	(0.0, 2.8)
		>40.0°C	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Fatigue ^d						
		Any	132	98 (74.2)	(65.9, 81.5)	130	59 (45.4)	(36.6, 54.3)
		Mild	132	28 (21.2)	(14.6, 29.2)	130	32 (24.6)	(17.5, 32.9)
		Moderate	132	65 (49.2)	(40.4, 58.1)	130	26 (20.0)	(13.5, 27.9)
		Severe	132	5 (3.8)	(1.2, 8.6)	130	1 (0.8)	(0.0, 4.2)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Headache ^d						
		Any	132	87 (65.9)	(57.2, 73.9)	130	55 (42.3)	(33.7, 51.3)
		Mild	132	33 (25.0)	(17.9, 33.3)	130	40 (30.8)	(23.0, 39.5)
		Moderate	132	53 (40.2)	(31.7, 49.0)	130	14 (10.8)	(6.0, 17.4)

Table 6. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
		Severe	132	1 (0.8)	(0.0, 4.1)	130	1 (0.8)	(0.0, 4.2)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Chills ^d						
		Any	132	49 (37.1)	(28.9, 46.0)	130	24 (18.5)	(12.2, 26.2)
		Mild	132	26 (19.7)	(13.3, 27.5)	130	16 (12.3)	(7.2, 19.2)
		Moderate	132	18 (13.6)	(8.3, 20.7)	130	6 (4.6)	(1.7, 9.8)
		Severe	132	5 (3.8)	(1.2, 8.6)	130	2 (1.5)	(0.2, 5.4)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Vomiting ^e						
		Any	132	2 (1.5)	(0.2, 5.4)	130	4 (3.1)	(0.8, 7.7)
		Mild	132	2 (1.5)	(0.2, 5.4)	130	4 (3.1)	(0.8, 7.7)
		Moderate	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Severe	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Diarrhea ^f						
		Any	132	19 (14.4)	(8.9, 21.6)	130	12 (9.2)	(4.9, 15.6)
		Mild	132	15 (11.4)	(6.5, 18.0)	130	10 (7.7)	(3.8, 13.7)
		Moderate	132	4 (3.0)	(0.8, 7.6)	130	2 (1.5)	(0.2, 5.4)
		Severe	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		New or worsened muscle pain ^d						
		Any	132	53 (40.2)	(31.7, 49.0)	130	17 (13.1)	(7.8, 20.1)
		Mild	132	19 (14.4)	(8.9, 21.6)	130	10 (7.7)	(3.8, 13.7)
		Moderate	132	32 (24.2)	(17.2, 32.5)	130	7 (5.4)	(2.2, 10.8)

Table 6. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
Non-Hispanic/non-Latino	1	Severe	132	2 (1.5)	(0.2, 5.4)	130	0	(0.0, 2.8)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		New or worsened joint pain ^d						
		Any	132	22 (16.7)	(10.7, 24.1)	130	8 (6.2)	(2.7, 11.8)
		Mild	132	11 (8.3)	(4.2, 14.4)	130	5 (3.8)	(1.3, 8.7)
		Moderate	132	9 (6.8)	(3.2, 12.5)	130	3 (2.3)	(0.5, 6.6)
		Severe	132	2 (1.5)	(0.2, 5.4)	130	0	(0.0, 2.8)
		Grade 4	132	0	(0.0, 2.8)	130	0	(0.0, 2.8)
		Any systemic event ^g	132	113 (85.6)	(78.4, 91.1)	130	81 (62.3)	(53.4, 70.7)
		Use of antipyretic or pain medication ^h	132	70 (53.0)	(44.2, 61.8)	130	15 (11.5)	(6.6, 18.3)
		Fever						
		≥38.0°C	993	97 (9.8)	(8.0, 11.8)	994	9 (0.9)	(0.4, 1.7)
		≥38.0°C to 38.4°C	993	61 (6.1)	(4.7, 7.8)	994	6 (0.6)	(0.2, 1.3)
		>38.4°C to 38.9°C	993	27 (2.7)	(1.8, 3.9)	994	1 (0.1)	(0.0, 0.6)
		>38.9°C to 40.0°C	993	8 (0.8)	(0.3, 1.6)	994	2 (0.2)	(0.0, 0.7)
		>40.0°C	993	1 (0.1)	(0.0, 0.6)	994	0	(0.0, 0.4)
		Fatigue ^d						
		Any	993	598 (60.2)	(57.1, 63.3)	994	402 (40.4)	(37.4, 43.6)
		Mild	993	243 (24.5)	(21.8, 27.3)	994	217 (21.8)	(19.3, 24.5)
		Moderate	993	341 (34.3)	(31.4, 37.4)	994	178 (17.9)	(15.6, 20.4)
		Severe	993	14 (1.4)	(0.8, 2.4)	994	7 (0.7)	(0.3, 1.4)
		Grade 4	993	0	(0.0, 0.4)	994	0	(0.0, 0.4)
		Headache ^d						

Table 6. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
		Any	993	551 (55.5)	(52.3, 58.6)	994	355 (35.7)	(32.7, 38.8)
		Mild	993	319 (32.1)	(29.2, 35.1)	994	224 (22.5)	(20.0, 25.3)
		Moderate	993	221 (22.3)	(19.7, 25.0)	994	123 (12.4)	(10.4, 14.6)
		Severe	993	11 (1.1)	(0.6, 2.0)	994	8 (0.8)	(0.3, 1.6)
		Grade 4	993	0	(0.0, 0.4)	994	0	(0.0, 0.4)
		Chills ^d						
		Any	993	281 (28.3)	(25.5, 31.2)	994	93 (9.4)	(7.6, 11.3)
		Mild	993	171 (17.2)	(14.9, 19.7)	994	70 (7.0)	(5.5, 8.8)
		Moderate	993	106 (10.7)	(8.8, 12.8)	994	23 (2.3)	(1.5, 3.5)
		Severe	993	4 (0.4)	(0.1, 1.0)	994	0	(0.0, 0.4)
		Grade 4	993	0	(0.0, 0.4)	994	0	(0.0, 0.4)
		Vomiting ^e						
		Any	993	30 (3.0)	(2.0, 4.3)	994	9 (0.9)	(0.4, 1.7)
		Mild	993	29 (2.9)	(2.0, 4.2)	994	7 (0.7)	(0.3, 1.4)
		Moderate	993	0	(0.0, 0.4)	994	2 (0.2)	(0.0, 0.7)
		Severe	993	1 (0.1)	(0.0, 0.6)	994	0	(0.0, 0.4)
		Grade 4	993	0	(0.0, 0.4)	994	0	(0.0, 0.4)
		Diarrhea ^f						
		Any	993	80 (8.1)	(6.4, 9.9)	994	74 (7.4)	(5.9, 9.3)
		Mild	993	69 (6.9)	(5.4, 8.7)	994	65 (6.5)	(5.1, 8.3)
		Moderate	993	11 (1.1)	(0.6, 2.0)	994	9 (0.9)	(0.4, 1.7)
		Severe	993	0	(0.0, 0.4)	994	0	(0.0, 0.4)
		Grade 4	993	0	(0.0, 0.4)	994	0	(0.0, 0.4)
		New or worsened muscle pain ^d						

Table 6. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
	2	Any	993	243 (24.5)	(21.8, 27.3)	994	136 (13.7)	(11.6, 16.0)
		Mild	993	110 (11.1)	(9.2, 13.2)	994	80 (8.0)	(6.4, 9.9)
		Moderate	993	131 (13.2)	(11.1, 15.5)	994	56 (5.6)	(4.3, 7.3)
		Severe	993	2 (0.2)	(0.0, 0.7)	994	0	(0.0, 0.4)
		Grade 4	993	0	(0.0, 0.4)	994	0	(0.0, 0.4)
		New or worsened joint pain ^d						
		Any	993	100 (10.1)	(8.3, 12.1)	994	71 (7.1)	(5.6, 8.9)
		Mild	993	61 (6.1)	(4.7, 7.8)	994	46 (4.6)	(3.4, 6.1)
		Moderate	993	38 (3.8)	(2.7, 5.2)	994	25 (2.5)	(1.6, 3.7)
		Severe	993	1 (0.1)	(0.0, 0.6)	994	0	(0.0, 0.4)
		Grade 4	993	0	(0.0, 0.4)	994	0	(0.0, 0.4)
		Any systemic event ^g	993	777 (78.2)	(75.5, 80.8)	994	562 (56.5)	(53.4, 59.6)
		Use of antipyretic or pain medication ^h	993	362 (36.5)	(33.5, 39.5)	994	103 (10.4)	(8.5, 12.4)
		Fever						
		≥38.0°C	967	203 (21.0)	(18.5, 23.7)	951	5 (0.5)	(0.2, 1.2)
		≥38.0°C to 38.4°C	967	101 (10.4)	(8.6, 12.5)	951	3 (0.3)	(0.1, 0.9)
		>38.4°C to 38.9°C	967	78 (8.1)	(6.4, 10.0)	951	1 (0.1)	(0.0, 0.6)
		>38.9°C to 40.0°C	967	24 (2.5)	(1.6, 3.7)	951	1 (0.1)	(0.0, 0.6)
		>40.0°C	967	0	(0.0, 0.4)	951	0	(0.0, 0.4)
		Fatigue ^d						
		Any	967	649 (67.1)	(64.1, 70.1)	951	234 (24.6)	(21.9, 27.5)
		Mild	967	207 (21.4)	(18.9, 24.1)	951	116 (12.2)	(10.2, 14.4)
		Moderate	967	420 (43.4)	(40.3, 46.6)	951	114 (12.0)	(10.0, 14.2)

Table 6. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
		Severe	967	22 (2.3)	(1.4, 3.4)	951	4 (0.4)	(0.1, 1.1)
		Grade 4	967	0	(0.0, 0.4)	951	0	(0.0, 0.4)
		Headache ^d						
		Any	967	641 (66.3)	(63.2, 69.3)	951	237 (24.9)	(22.2, 27.8)
		Mild	967	273 (28.2)	(25.4, 31.2)	951	150 (15.8)	(13.5, 18.2)
		Moderate	967	347 (35.9)	(32.9, 39.0)	951	86 (9.0)	(7.3, 11.0)
		Severe	967	21 (2.2)	(1.3, 3.3)	951	1 (0.1)	(0.0, 0.6)
		Grade 4	967	0	(0.0, 0.4)	951	0	(0.0, 0.4)
		Chills ^d						
		Any	967	418 (43.2)	(40.1, 46.4)	951	63 (6.6)	(5.1, 8.4)
		Mild	967	202 (20.9)	(18.4, 23.6)	951	46 (4.8)	(3.6, 6.4)
		Moderate	967	200 (20.7)	(18.2, 23.4)	951	17 (1.8)	(1.0, 2.8)
		Severe	967	16 (1.7)	(0.9, 2.7)	951	0	(0.0, 0.4)
		Grade 4	967	0	(0.0, 0.4)	951	0	(0.0, 0.4)
		Vomiting ^e						
		Any	967	28 (2.9)	(1.9, 4.2)	951	8 (0.8)	(0.4, 1.7)
		Mild	967	24 (2.5)	(1.6, 3.7)	951	7 (0.7)	(0.3, 1.5)
		Moderate	967	4 (0.4)	(0.1, 1.1)	951	1 (0.1)	(0.0, 0.6)
		Severe	967	0	(0.0, 0.4)	951	0	(0.0, 0.4)
		Grade 4	967	0	(0.0, 0.4)	951	0	(0.0, 0.4)
		Diarrhea ^f						
		Any	967	53 (5.5)	(4.1, 7.1)	951	38 (4.0)	(2.8, 5.4)
		Mild	967	49 (5.1)	(3.8, 6.6)	951	34 (3.6)	(2.5, 5.0)
		Moderate	967	4 (0.4)	(0.1, 1.1)	951	4 (0.4)	(0.1, 1.1)

Table 6. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Systemic Event	Vaccine Group (as Administered)				
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)	
		Severe	967	0 (0.0, 0.4)	951	0 (0.0, 0.4)	
		Grade 4	967	0 (0.0, 0.4)	951	0 (0.0, 0.4)	
		New or worsened muscle pain ^d					
		Any	967	313 (32.4) (29.4, 35.4)	951	84 (8.8) (7.1, 10.8)	
		Mild	967	134 (13.9) (11.7, 16.2)	951	48 (5.0) (3.7, 6.6)	
		Moderate	967	175 (18.1) (15.7, 20.7)	951	34 (3.6) (2.5, 5.0)	
		Severe	967	4 (0.4) (0.1, 1.1)	951	2 (0.2) (0.0, 0.8)	
		Grade 4	967	0 (0.0, 0.4)	951	0 (0.0, 0.4)	
		New or worsened joint pain ^d					
		Any	967	155 (16.0) (13.8, 18.5)	951	49 (5.2) (3.8, 6.8)	
		Mild	967	82 (8.5) (6.8, 10.4)	951	29 (3.0) (2.1, 4.4)	
		Moderate	967	71 (7.3) (5.8, 9.2)	951	20 (2.1) (1.3, 3.2)	
		Severe	967	2 (0.2) (0.0, 0.7)	951	0 (0.0, 0.4)	
		Grade 4	967	0 (0.0, 0.4)	951	0 (0.0, 0.4)	
		Any systemic event ^g	967	807 (83.5) (81.0, 85.7)	951	388 (40.8) (37.7, 44.0)	
		Use of antipyretic or pain medication ^h	967	501 (51.8) (48.6, 55.0)	951	86 (9.0) (7.3, 11.0)	
	Any dose	Fever					
		≥38.0°C	997	250 (25.1) (22.4, 27.9)	996	13 (1.3) (0.7, 2.2)	
		≥38.0°C to 38.4°C	997	125 (12.5) (10.5, 14.8)	996	8 (0.8) (0.3, 1.6)	
		>38.4°C to 38.9°C	997	94 (9.4) (7.7, 11.4)	996	2 (0.2) (0.0, 0.7)	
		>38.9°C to 40.0°C	997	30 (3.0) (2.0, 4.3)	996	3 (0.3) (0.1, 0.9)	
		>40.0°C	997	1 (0.1) (0.0, 0.6)	996	0 (0.0, 0.4)	
		Fatigue ^d					

Table 6. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%)	(95% CI) ^c	N ^a	Placebo n ^b (%)	(95% CI) ^c
		Any	997	777 (77.9)	(75.2, 80.5)	996	476 (47.8)	(44.6, 50.9)
		Mild	997	211 (21.2)	(18.7, 23.8)	996	231 (23.2)	(20.6, 25.9)
		Moderate	997	531 (53.3)	(50.1, 56.4)	996	234 (23.5)	(20.9, 26.3)
		Severe	997	35 (3.5)	(2.5, 4.8)	996	11 (1.1)	(0.6, 2.0)
		Grade 4	997	0	(0.0, 0.4)	996	0	(0.0, 0.4)
		Headache ^d						
		Any	997	766 (76.8)	(74.1, 79.4)	996	451 (45.3)	(42.2, 48.4)
		Mild	997	291 (29.2)	(26.4, 32.1)	996	263 (26.4)	(23.7, 29.3)
		Moderate	997	445 (44.6)	(41.5, 47.8)	996	180 (18.1)	(15.7, 20.6)
		Severe	997	30 (3.0)	(2.0, 4.3)	996	8 (0.8)	(0.3, 1.6)
		Grade 4	997	0	(0.0, 0.4)	996	0	(0.0, 0.4)
		Chills ^d						
		Any	997	508 (51.0)	(47.8, 54.1)	996	135 (13.6)	(11.5, 15.8)
		Mild	997	231 (23.2)	(20.6, 25.9)	996	98 (9.8)	(8.1, 11.9)
		Moderate	997	258 (25.9)	(23.2, 28.7)	996	37 (3.7)	(2.6, 5.1)
		Severe	997	19 (1.9)	(1.2, 3.0)	996	0	(0.0, 0.4)
		Grade 4	997	0	(0.0, 0.4)	996	0	(0.0, 0.4)
		Vomiting ^e						
		Any	997	57 (5.7)	(4.4, 7.3)	996	16 (1.6)	(0.9, 2.6)
		Mild	997	52 (5.2)	(3.9, 6.8)	996	13 (1.3)	(0.7, 2.2)
		Moderate	997	4 (0.4)	(0.1, 1.0)	996	3 (0.3)	(0.1, 0.9)
		Severe	997	1 (0.1)	(0.0, 0.6)	996	0	(0.0, 0.4)
		Grade 4	997	0	(0.0, 0.4)	996	0	(0.0, 0.4)
		Diarrhea ^f						

Table 6. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

Ethnicity	Dose	Systemic Event	Vaccine Group (as Administered)					
			N ^a	BNT162b2 (30 µg) n ^b (%) (95% CI ^c)	N ^a	Placebo n ^b (%) (95% CI ^c)		
		Any	997	122 (12.2) (10.3, 14.4)	996	94 (9.4) (7.7, 11.4)		
		Mild	997	108 (10.8) (9.0, 12.9)	996	81 (8.1) (6.5, 10.0)		
		Moderate	997	14 (1.4) (0.8, 2.3)	996	13 (1.3) (0.7, 2.2)		
		Severe	997	0 (0.0, 0.4)	996	0 (0.0, 0.4)		
		Grade 4	997	0 (0.0, 0.4)	996	0 (0.0, 0.4)		
		New or worsened muscle pain ^d						
		Any	997	422 (42.3) (39.2, 45.5)	996	179 (18.0) (15.6, 20.5)		
		Mild	997	167 (16.8) (14.5, 19.2)	996	100 (10.0) (8.2, 12.1)		
		Moderate	997	249 (25.0) (22.3, 27.8)	996	77 (7.7) (6.1, 9.6)		
		Severe	997	6 (0.6) (0.2, 1.3)	996	2 (0.2) (0.0, 0.7)		
		Grade 4	997	0 (0.0, 0.4)	996	0 (0.0, 0.4)		
		New or worsened joint pain ^d						
		Any	997	207 (20.8) (18.3, 23.4)	996	99 (9.9) (8.2, 12.0)		
		Mild	997	111 (11.1) (9.2, 13.3)	996	58 (5.8) (4.5, 7.5)		
		Moderate	997	93 (9.3) (7.6, 11.3)	996	41 (4.1) (3.0, 5.5)		
		Severe	997	3 (0.3) (0.1, 0.9)	996	0 (0.0, 0.4)		
		Grade 4	997	0 (0.0, 0.4)	996	0 (0.0, 0.4)		
		Any systemic event ^g	997	911 (91.4) (89.5, 93.0)	996	642 (64.5) (61.4, 67.4)		
		Use of antipyretic or pain medication ^h	997	592 (59.4) (56.3, 62.4)	996	161 (16.2) (13.9, 18.6)		

Table 6. Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Ethnicity – Subjects 12 Through 15 Years of Age – Safety Population

			Vaccine Group (as Administered)					
Ethnicity	Dose	Systemic Event	BNT162b2 (30 µg)			Placebo		
			N ^a	n ^b (%)	(95% CI) ^c	N ^a	n ^b (%)	(95% CI) ^c
Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person.								
Note: Subject C4591001 1077 10771278 (13 years of age) experienced systemic events, including a temperature of 40.4°C, on the day of Dose 2. Since these events were recorded as adverse events and not in the e-diary, they do not appear in this table.								
a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.								
b. n = Number of subjects with the specified characteristic.								
c. Exact 2-sided CI based on the Clopper and Pearson method.								
d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe chills, severe muscle pain, or severe joint pain.								
e. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.								
f. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours; Grade 4: emergency room 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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