Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup
– Blinded Placebo-Controlled Follow-up Period
– Subjects ≥16 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2
– Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21047)		Placebo (N[a]=21210)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	81	6.340 (20533)	854	6.110 (20595)	90.9	(88.5, 92.8)
Age group (years)						
16 to 55	56	3.766 (12088)	584	3.619 (12142)	90.8	(87.9, 93.1)
>55	25	2.573 (8445)	270	2.492 (8453)	91.0	(86.5, 94.3)
≥65	7	1.267 (4315)	128	1.232 (4326)	94.7	(88.7, 97.9)
16 to 17	0	0.065 (365)	11	0.061 (355)	100.0	(62.4, 100.0)
16 to 25	10	0.511 (1734)	84	0.498 (1740)	88.4	(77.6, 94.6)
16 to 64	74	5.073 (16218)	726	4.879 (16269)	90.2	(87.5, 92.4)
18 to 64	74	5.008 (15853)	715	4.817 (15914)	90.0	(87.3, 92.3)
55 to 64	21	1.442 (4563)	158	1.386 (4559)	87.2	(79.8, 92.3)
65 to 74	6	1.021 (3450)	102	0.992 (3468)	94.3	(87.1, 98.0)
≥75	1	0.246 (865)	26	0.240 (858)	96.2	(77.2, 99.9)
75 to 85	1	0.244 (860)	25	0.238 (852)	96.1	(76.2, 99.9)
>85	0	0.001 (5)	1	0.001 (6)	100.0	(-4055.9, 100.0)
Sex						
Male	44	3.289 (10548)	399	3.097 (10354)	89.6	(85.8, 92.6)

Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup
– Blinded Placebo-Controlled Follow-up Period
– Subjects ≥16 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2
– Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21047)		Placebo (N[a]=21210)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Female	37	3.051 (9985)	455	3.013 (10241)	92.0	(88.8, 94.4)
Race						
White	69	5.234 (16846)	749	5.054 (16952)	91.1	(88.6, 93.2)
Black or African American	4	0.602 (1909)	49	0.591 (1928)	92.0	(78.1, 97.9)
American Indian or Alaska Native	0	0.043 (196)	3	0.038 (180)	100.0	(-116.0, 100.0)
Asian	3	0.258 (907)	24	0.247 (896)	88.0	(60.6, 97.7)
Native Hawaiian or other Pacific Islander	0	0.016 (54)	1	0.008 (31)	100.0	(-1947.9, 100.0)
Multiracial	5	0.160 (538)	22	0.140 (503)	80.1	(46.1, 94.1)
Not reported	0	0.027 (83)	6	0.031 (105)	100.0	(1.4, 100.0)
All others[f]	8	0.504 (1778)	56	0.465 (1715)	86.8	(72.2, 94.6)
Ethnicity						
Hispanic/Latino	32	1.841 (5280)	240	1.777 (5266)	87.1	(81.3, 91.4)
Non-Hispanic/non-Latino	48	4.466 (15149)	614	4.300 (15220)	92.5	(89.9, 94.5)
Not reported	1	0.032 (104)	0	0.034 (109)	-∞	(NA, NA)
Country						
Argentina	16	1.033 (2655)	110	1.017 (2670)	85.7	(75.7, 92.1)
Brazil	14	0.441 (1419)	82	0.408 (1401)	84.2	(71.9, 91.7)

Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup
– Blinded Placebo-Controlled Follow-up Period
– Subjects ≥16 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2
– Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21047)		Placebo (N[a]=21210)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Germany	0	0.047 (237)	1	0.048 (243)	100.0	(-3868.6, 100.0)
South Africa	0	0.099 (358)	10	0.096 (358)	100.0	(56.6, 100.0)
Turkey	0	0.029 (238)	6	0.026 (232)	100.0	(22.2, 100.0)
USA	51	4.692 (15626)	645	4.515 (15691)	92.4	(89.9, 94.4)
Prior SARS-CoV-2 Status						
Positive at baseline[g]	3	0.183 (593)	6	0.195 (643)	46.7	(-149.5, 91.4)
Positive N-binding only	2	0.143 (466)	5	0.147 (488)	58.8	(-151.9, 96.1)
Positive NAAT only	0	0.013 (43)	1	0.014 (48)	100.0	(-3922.5, 100.0)
Positive NAAT and N-binding	1	0.027 (84)	0	0.034 (106)	-∞	(NA, NA)
Negative at baseline but positive prior to 7 days after Dose 2[h]	0	0.011 (40)	1	0.013 (50)	100.0	(-4759.2, 100.0)
Negative prior to 7 days after Dose 2[i]	77	6.092 (19711)	833	5.856 (19740)	91.1	(88.8, 93.1)
Unknown	1	0.054 (189)	14	0.046 (162)	93.9	(59.9, 99.9)

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

a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.

Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup
– Blinded Placebo-Controlled Follow-up Period
– Subjects ≥16 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2
– Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21047)		Placebo (N[a]=21210)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
g. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
h. Negative N-binding antibody result and negative NAAT result at Visit 1, positive NAAT result at Visit 2 or at unscheduled visit, if any, prior to 7 days after Dose 2.
i. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1 and Visit 2, and negative NAAT result at unscheduled visit, if any, prior to 7 days after Dose 2.
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Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup
– Blinded Placebo-Controlled Follow-up Period
– Subjects ≥16 Years of Age and Without Evidence of Infection Prior to 7 Days After Dose 2
– Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19993)		Placebo (N[a]=20118)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	77	6.092 (19711)	833	5.857 (19741)	91.1	(88.8, 93.1)
Age group (years)						
16 to 55	52	3.593 (11517)	568	3.439 (11533)	91.2	(88.3, 93.5)
>55	25	2.499 (8194)	265	2.417 (8208)	90.9	(86.2, 94.2)
≥65	7	1.233 (4192)	124	1.202 (4226)	94.5	(88.3, 97.8)
16 to 17	0	0.061 (342)	10	0.057 (331)	100.0	(58.2, 100.0)
16 to 25	8	0.482 (1629)	80	0.466 (1622)	90.3	(80.0, 96.0)
16 to 64	70	4.859 (15519)	709	4.654 (15515)	90.5	(87.9, 92.7)
18 to 64	70	4.798 (15177)	699	4.597 (15184)	90.4	(87.7, 92.6)
55 to 64	21	1.399 (4426)	156	1.334 (4388)	87.2	(79.7, 92.3)
65 to 74	6	0.994 (3350)	98	0.966 (3379)	94.1	(86.6, 97.9)
≥75	1	0.239 (842)	26	0.237 (847)	96.2	(76.9, 99.9)
75 to 85	1	0.238 (837)	25	0.235 (841)	96.0	(75.9, 99.9)
>85	0	0.001 (5)	1	0.001 (6)	100.0	(-4055.9, 100.0)
Sex						
Male	42	3.167 (10138)	389	2.972 (9934)	89.9	(86.0, 92.8)

Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup
– Blinded Placebo-Controlled Follow-up Period
– Subjects ≥16 Years of Age and Without Evidence of Infection Prior to 7 Days After Dose 2
– Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19993)		Placebo (N[a]=20118)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Female	35	2.926 (9573)	444	2.885 (9807)	92.2	(89.0, 94.7)
Race						
White	67	5.076 (16321)	730	4.902 (16432)	91.1	(88.6, 93.2)
Black or African American	4	0.537 (1697)	48	0.519 (1690)	92.0	(78.0, 97.9)
American Indian or Alaska Native	0	0.040 (183)	3	0.037 (175)	100.0	(-120.7, 100.0)
Asian	3	0.251 (883)	23	0.239 (869)	87.6	(58.9, 97.6)
Native Hawaiian or other Pacific Islander	0	0.015 (51)	1	0.008 (30)	100.0	(-2017.6, 100.0)
Multiracial	3	0.148 (497)	22	0.124 (447)	88.6	(62.1, 97.8)
Not reported	0	0.025 (79)	6	0.029 (98)	100.0	(3.8, 100.0)
All others[f]	6	0.480 (1693)	55	0.436 (1619)	90.1	(77.0, 96.5)
Ethnicity						
Hispanic/Latino	29	1.768 (5052)	236	1.696 (5015)	88.2	(82.6, 92.3)
Non-Hispanic/non-Latino	47	4.293 (14559)	597	4.128 (14620)	92.4	(89.8, 94.5)
Not reported	1	0.031 (100)	0	0.033 (106)	-∞	(NA, NA)
Country						
Argentina	15	1.012 (2600)	108	0.986 (2586)	86.5	(76.7, 92.7)
Brazil	12	0.406 (1311)	80	0.374 (1293)	86.2	(74.5, 93.1)

Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup
– Blinded Placebo-Controlled Follow-up Period
– Subjects ≥16 Years of Age and Without Evidence of Infection Prior to 7 Days After Dose 2
– Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19993)		Placebo (N[a]=20118)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Germany	0	0.047 (236)	1	0.048 (242)	100.0	(-3874.2, 100.0)
South Africa	0	0.080 (291)	9	0.074 (276)	100.0	(53.5, 100.0)
Turkey	0	0.027 (228)	5	0.025 (222)	100.0	(-0.1, 100.0)
USA	50	4.519 (15045)	630	4.350 (15122)	92.4	(89.8, 94.4)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
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Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects ≥16 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21047)		Placebo (N[a]=21210)			
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**
First severe COVID-19 occurrence based on CDC-definition from 7 days after Dose 2	0	6.345 (20513)	31	6.225 (20593)	100.0	(87.6, 100.0)

Abbreviation: VE = vaccine efficacy.

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

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

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

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

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

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Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects ≥16 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=21047)		Placebo (N[a]=21210)				
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**	**Pr (VE >30% | data)[f]**
First severe COVID-19 occurrence from 7 days after Dose 2	1	6.353 (20540)	21	6.237 (20629)	95.3	(70.9, 99.9)	>0.9999

Abbreviation: VE = vaccine efficacy.

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

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

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

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

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

f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.

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