Table.A.1 Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Test Status – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population, Participants 16 Years of Age and Older (Data Cutoff March 13, 2021)

RT-PCR NP Swab Results and Serostatus at Different Time Points	BNT162b2 (N[a]=21047) Cases n1[b] Surveillance Time[c] (n2[d])	Placebo (N[a]=21210) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
Pre-Dose 1 SARS-CoV-2 RT-PCR (NP swab)			
Positive	1 0.040 (127)	1 0.047 (154)	-17.9 (-9154.3, 98.5)
Negative	79 6.284 (20356)	853 6.048 (20395)	91.1 (88.8, 93.0)
Unknown	1 0.015 (50)	0 0.015 (46)	-∞ (NA, NA)
Pre-Dose 2 SARS-CoV-2 RT-PCR (NP swab)			
Positive	1 0.030 (101)	1 0.037 (130)	-24.7 (-9685.9, 98.4)
Negative	80 6.293 (20376)	849 6.061 (20423)	90.9 (88.6, 92.9)
Unknown	0 0.017 (56)	4 0.013 (42)	100.0 (-11.3, 100.0)

Table.A.1 Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Test Status – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population, Participants 16 Years of Age and Older (Data Cutoff March 13, 2021)

RT-PCR NP Swab Results and Serostatus at Different Time Points	BNT162b2 (N[a]=21047) Cases n1[b] Surveillance Time[c] (n2[d])	Placebo (N[a]=21210) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
Subjects with negative PCR Pre-dose 1 and positive PCR Pre-dose 2			
Subjects with documented COVID-19 symptoms between Dose 1 and 2	0 0.000 (0)	0 0.001 (2)	
Subjects with no documented COVID-19 symptoms between Dose 1 and 2	0 0.016 (58)	1 0.019 (71)	
Pre-Dose 1 N-binding antibody			
Positive	3 0.169 (550)	5 0.181 (594)	36.0 (-228.7, 90.1)
Negative	78 6.147 (19896)	847 5.910 (19927)	91.1 (88.8, 93.1)
Unknown	0 0.023 (87)	2 0.019 (74)	100.0 (-348.8, 100.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NA = Not applicable; NP = nasopharyngeal; RT-PCR = reverse transcription–polymerase chain reaction; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

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

Table.A.1 Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Test Status – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population, Participants 16 Years of Age and Older (Data Cutoff March 13, 2021)

RT-PCR NP Swab Results and Serostatus at Different Time Points	BNT162b2 (N^a=21047) Cases n1[b] Surveillance Time[c] (n2[d])	Placebo (N^a=21210) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]

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.

Table.A.2 Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Test Status – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population, Participants 16 Years of Age and Older (Data Cutoff March 13, 2021)

RT-PCR NP Swab Results and Serostatus at Different Time Points	BNT162b2 (N[a]=21552) Cases n1[b] Surveillance Time[c] (n2[d])	Placebo (N[a]=21528) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
Pre-Dose 1 SARS-CoV-2 RT-PCR (NP swab)			
Positive	1 0.041 (132)	1 0.048 (155)	-15.4 (-8959.5, 98.5)
Negative	80 6.422 (20836)	869 6.144 (20697)	91.2 (88.9, 93.1)
Unknown	1 0.016 (51)	0 0.016 (49)	-∞ (NA, NA)
Pre-Dose 2 SARS-CoV-2 RT-PCR (NP swab)			
Positive	1 0.031 (105)	1 0.038 (131)	-22.3 (-9503.8, 98.4)
Negative	81 6.431 (20857)	865 6.156 (20723)	91.0 (88.7, 93.0)
Unknown	0 0.017 (57)	4 0.013 (47)	100.0 (-16.4, 100.0)

Table.A.2 Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Test Status – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population, Participants 16 Years of Age and Older (Data Cutoff March 13, 2021)

RT-PCR NP Swab Results and Serostatus at Different Time Points	BNT162b2 (N[a]=21552) Cases n1[b] Surveillance Time[c] (n2[d])	Placebo (N[a]=21528) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
Subjects with negative PCR Pre-dose 1 and positive PCR Pre-dose 2			
Subjects with documented COVID-19 symptoms between Dose 1 and 2	0 0.000 (0)	0 0.001 (2)	
Subjects with no documented COVID-19 symptoms between Dose 1 and 2	0 0.016 (61)	1 0.020 (72)	
Pre-Dose 1 N-binding antibody			
Positive	3 0.173 (563)	5 0.185 (608)	35.8 (-229.9, 90.0)
Negative	79 6.283 (20367)	863 6.002 (20218)	91.3 (89.0, 93.1)
Unknown	0 0.023 (89)	2 0.019 (75)	100.0 (-344.1, 100.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NA = Not applicable; NP = nasopharyngeal; RT-PCR = reverse transcription–polymerase chain reaction; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

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

Table.A.2 Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Test Status – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population, Participants 16 Years of Age and Older (Data Cutoff March 13, 2021)

RT-PCR NP Swab Results and Serostatus at Different Time Points	BNT162b2 (N^a=21552) Cases n1[b] Surveillance Time[c] (n2[d])	Placebo (N^a=21528) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]

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.

Table.D Disposition of Participants 16 Years of Age and Older, Phase 2/3 Subjects, Efficacy Population (Data Cutoff March 13, 2021)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	**Placebo n[a] (%)**	**Total n[a] (%)**
Randomized[b]	22085 (100.0)	22080 (100.0)	44165 (100.0)
Dose 1 all-available efficacy population	22009 (99.7)	22008 (99.7)	44017 (99.7)
Subjects without evidence of infection before Dose 1	21172 (95.9)	21168 (95.9)	42340 (95.9)
Subjects excluded from Dose 1 all-available efficacy population	76 (0.3)	72 (0.3)	148 (0.3)
Reason for exclusion[c]			
Did not receive at least 1 vaccination	55 (0.2)	50 (0.2)	105 (0.2)
Data considered potentially unreliable due to lack of PI oversight identified as significant quality event	21 (0.1)	22 (0.1)	43 (0.1)
Dose 2 all-available efficacy population	21648 (98.0)	21624 (97.9)	43272 (98.0)
Subjects without evidence of infection prior to 7 days after Dose 2	20536 (93.0)	20487 (92.8)	41023 (92.9)
Subjects excluded from Dose 2 all-available efficacy population	437 (2.0)	456 (2.1)	893 (2.0)
Reason for exclusion[c]			
Did not receive 2 vaccinations	374 (1.7)	430 (1.9)	804 (1.8)
Data considered potentially unreliable due to lack of PI oversight identified as significant quality event	21 (0.1)	22 (0.1)	43 (0.1)
Unblinded prior to 7 days after Dose 2	44 (0.2)	11 (0.0)	55 (0.1)
Evaluable efficacy (7 days) population	21136 (95.7)	21300 (96.5)	42436 (96.1)
Subjects without evidence of infection prior to 7 days after Dose 2	20064 (90.8)	20197 (91.5)	40261 (91.2)
Subjects excluded from evaluable efficacy (7 days) population	949 (4.3)	780 (3.5)	1729 (3.9)
Reason for exclusion[c]			

Table.D Disposition of Participants 16 Years of Age and Older, Phase 2/3 Subjects, Efficacy Population (Data Cutoff March 13, 2021)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	**Placebo n[a] (%)**	**Total n[a] (%)**
Randomized but did not meet all eligibility criteria	32 (0.1)	30 (0.1)	62 (0.1)
Data considered potentially unreliable due to lack of PI oversight identified as significant quality event	21 (0.1)	22 (0.1)	43 (0.1)
Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	718 (3.3)	729 (3.3)	1447 (3.3)
Unblinded prior to 7 days after Dose 2	44 (0.2)	11 (0.0)	55 (0.1)
Had other important protocol deviations on or prior to 7 days after Dose 2	240 (1.1)	58 (0.3)	298 (0.7)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.

Table.F Demographics and Other Baseline Characteristics, Participants 16 Years of Age and Older, With or Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy Population (Data Cutoff March 13, 2021)

	Vaccine Group (as Randomized)		
Characteristic	**BNT162b2 (30 µg) (N[a]=21136) n[b] (%)**	**Placebo (N[a]=21300) n[b] (%)**	**Total (N[a]=42436) n[b] (%)**
Sex: Female	10280 (48.6)	10579 (49.7)	20859 (49.2)
Sex: Male	10856 (51.4)	10721 (50.3)	21577 (50.8)
Age at Vaccination: Mean years (SD)	49.8 (15.99)	49.7 (16.03)	49.7 (16.01)
Age at Vaccination: Median (years)	51.0	51.0	51.0
Age at Vaccination: Min, max (years)	(16, 89)	(16, 91)	(16, 91)
Age Group: 16 to <18 years	370 (1.8)	362 (1.7)	732 (1.7)
Age Group: 18 to 55 years	12120 (57.3)	12252 (57.5)	24372 (57.4)
Age Group: >55 years	8646 (40.9)	8686 (40.8)	17332 (40.8)
Age Group: ≥65 years	4407 (20.9)	4429 (20.8)	8836 (20.8)
Race: American Indian or Alaska Native	204 (1.0)	190 (0.9)	394 (0.9)
Race: Asian	929 (4.4)	924 (4.3)	1853 (4.4)
Race: Black or African American	2009 (9.5)	2036 (9.6)	4045 (9.5)
Race: Native Hawaiian or Other Pacific Islander	56 (0.3)	32 (0.2)	88 (0.2)
Race: White	17304 (81.9)	17487 (82.1)	34791 (82.0)
Race: Multiracial	545 (2.6)	519 (2.4)	1064 (2.5)
Race: Not reported	89 (0.4)	112 (0.5)	201 (0.5)
Ethnicity: Hispanic or Latino	5403 (25.6)	5409 (25.4)	10812 (25.5)

Table.F Demographics and Other Baseline Characteristics, Participants 16 Years of Age and Older, With or Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy Population (Data Cutoff March 13, 2021)

Characteristic	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=21136) n[b] (%)	Placebo (N[a]=21300) n[b] (%)	Total (N[a]=42436) n[b] (%)
Ethnicity: Not Hispanic or Latino	15628 (73.9)	15778 (74.1)	31406 (74.0)
Ethnicity: Not reported	105 (0.5)	113 (0.5)	218 (0.5)
Obesity: Yes[c]	7239 (34.2)	7386 (34.7)	14625 (34.5)
Obesity: No	13897 (65.8)	13914 (65.3)	27811 (65.5)
Comorbidities: Yes[d]	9712 (46.0)	9736 (45.7)	19448 (45.8)
Comorbidities: No	11424 (54.0)	11564 (54.3)	22988 (54.2)
Baseline evidence of prior SARS-CoV-2 infection: Negative[f]	20365 (96.4)	20511 (96.3)	40876 (96.3)
Baseline evidence of prior SARS-CoV-2 infection: Positive[e]	627 (3.0)	669 (3.1)	1296 (3.1)
Baseline evidence of prior SARS-CoV-2 infection: Missing	144 (0.7)	120 (0.6)	264 (0.6)
Country: Argentina	2686 (12.7)	2710 (12.7)	5396 (12.7)
Country: Brazil	1437 (6.8)	1432 (6.7)	2869 (6.8)
Country: Germany	240 (1.1)	243 (1.1)	483 (1.1)
Country: South Africa	391 (1.8)	392 (1.8)	783 (1.8)
Country: Turkey	241 (1.1)	238 (1.1)	479 (1.1)
Country: United States of America	16141 (76.4)	16285 (76.5)	32426 (76.4)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Subjects who had BMI ≥30 kg/m^2.

Table.F Demographics and Other Baseline Characteristics, Participants 16 Years of Age and Older, With or Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy Population (Data Cutoff March 13, 2021)

	Vaccine Group (as Randomized)		
Characteristic	**BNT162b2 (30 µg) (N^a=21136) n^b (%)**	**Placebo (N^a=21300) n^b (%)**	**Total (N^a=42436) n^b (%)**

d. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2.
e. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
f. Negative N-binding antibody result and negative NAAT result at Visit 1 and no medical history of COVID-19.

Table.G Final Analysis of Efficacy of BNT162b2 Against Confirmed COVID-19 From 7 Days After Dose 2 in Participants Without Evidence of Prior SARS-CoV-2 Infection – Evaluable Efficacy Population, 16 Years and Older (Data Cutoff November 2020)

Pre-specified Age Group	BNT162b2 (N^a=18152) Cases n1[b] Surveillance Time[c] (n2[d])	Placebo (N^a=18283) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]	Met Predefined Success Criterion
All participants	8 2.214 (17397)	162 2.222 (17498)	95.0 (90.0, 97.9)	NA
16 to 55 years	5 1.234 (9897)	114 1.239 (9955)	95.6 (89.4, 98.6)	NA
>55 years and older	3 0.980 (7500)	48 0.983 (7543)	93.7 (80.6, 98.8)	NA

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.

Table.H Updated Efficacy of BNT162b2 Against Confirmed COVID-19 From 7 Days After Dose 2 in Participants Without Evidence of Prior SARS-CoV-2 Infection – Evaluable Efficacy Population, 16 Years and Older (Data Cutoff March 13, 2021)

Pre-specified Age Group	BNT162b2 (N[a]=19993) Cases n1[b] Surveillance Time[c] (n2[d])	Placebo (N[a]=20118) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
All participants	77 6.092 (19711)	833 5.857 (19741)	91.1 (88.8, 93.1)
16 to 55 years	52 3.593 (11517)	568 3.439 (11533)	91.2 (88.3, 93.5)
>55 years and older	25 2.499 (8194)	265 2.417 (8208)	90.9 (86.2, 94.2)

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.

Table.I Updated Efficacy of BNT162b2 Against Confirmed COVID-19 From 7 Days After Dose 2 in Participants With or Without Evidence of Prior SARS-CoV-2 Infection – Evaluable Efficacy Population, 16 Years and Older (Data Cutoff March 13, 2021)

Pre-specified Age Group	BNT162b2 (N[a]=21047) Cases n1[b] Surveillance Time[c] (n2[d])	Placebo (N[a]=21210) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
All participants	81 6.340 (20533)	854 6.110 (20595)	90.9 (88.5, 92.8)
16 to 55 years	56 3.766 (12088)	584 3.619 (12142)	90.8 (87.9, 93.1)
>55 years and older	25 2.573 (8445)	270 2.492 (8453)	91.0 (86.5, 94.3)

Abbreviations: 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.

Table.J Subgroup Analyses of Updated Second Primary Endpoint: First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup, Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy Population, 16 Years and Older (Data Cutoff March 13, 2021)

	Vaccine Group (as Randomized)		
Efficacy Endpoint Subgroup	**BNT162b2 (30 µg) (N[a]=21047) Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo (N[a]=21210) Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy (%) (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: 16 to <18 years	0 0.065 (365)	11 0.061 (355)	100.0 (62.4, 100.0)
Age group: 18 to <65 years	74 5.008 (15853)	715 4.817 (15914)	90.0 (87.3, 92.3)
Age group: ≥65 years	7 1.267 (4315)	128 1.232 (4326)	94.7 (88.7, 97.9)
Age group: 65 to 74 years	6 1.021 (3450)	102 0.992 (3468)	94.3 (87.1, 98.0)
Age group: ≥75 years	1 0.246 (865)	26 0.240 (858)	96.2 (77.2, 99.9)

Table.J Subgroup Analyses of Updated Second Primary Endpoint: First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup, Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy Population, 16 Years and Older (Data Cutoff March 13, 2021)

Efficacy Endpoint Subgroup	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=21047) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Group (as Randomized) Placebo (N[a]=21210) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy (%) (95% CI[e])
At risk: Yes[f]	36 2.887 (9359)	402 2.772 (9340)	91.4 (87.9, 94.1)
At risk: No	45 3.453 (11174)	452 3.338 (11255)	90.4 (86.9, 93.1)
Age group and Risk: 16-64 and not at risk	44 2.887 (9254)	397 2.779 (9289)	89.3 (85.4, 92.4)
Age group and Risk: 16-64 and at risk	30 2.186 (6964)	329 2.100 (6980)	91.2 (87.3, 94.2)
Age group and Risk: ≥65 and not at risk	1 0.566 (1920)	55 0.559 (1966)	98.2 (89.6, 100.0)
Age group and Risk: ≥65 and at risk	6 0.701 (2395)	73 0.672 (2360)	92.1 (82.0, 97.2)
Obese: Yes[g]	28 2.185 (6999)	314 2.139 (7111)	91.3 (87.1, 94.3)

Table.J Subgroup Analyses of Updated Second Primary Endpoint: First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup, Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy Population, 16 Years and Older (Data Cutoff March 13, 2021)

Efficacy Endpoint Subgroup	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=21047) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Group (as Randomized) Placebo (N[a]=21210) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy (%) (95% CI[e])
Obese: No	53 4.153 (13528)	540 3.970 (13478)	90.6 (87.5, 93.1)
Age group and obese:16-64 and not obese	49 3.303 (10629)	458 3.158 (10614)	89.8 (86.2, 92.5)
Age group and obese:16-64 and obese	25 1.768 (5584)	268 1.719 (5649)	90.9 (86.3, 94.2)
Age group and obese: ≥65 and not obese	4 0.850 (2899)	82 0.811 (2864)	95.3 (87.6, 98.8)
Age group and obese: ≥65 and obese	3 0.417 (1415)	46 0.420 (1462)	93.4 (79.5, 98.7)
Sex: Female	37 3.051 (9985)	455 3.013 (10241)	92.0 (88.8, 94.4)
Sex: Male	44 3.289 (10548)	399 3.097 (10354)	89.6 (85.8, 92.6)

Table.J Subgroup Analyses of Updated Second Primary Endpoint: First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup, Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy Population, 16 Years and Older (Data Cutoff March 13, 2021)

Efficacy Endpoint Subgroup	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=21047) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Group (as Randomized) Placebo (N[a]=21210) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy (%) (95% CI[e])
Ethnicity: Hispanic or Latino	32 1.841 (5280)	240 1.777 (5266)	87.1 (81.3, 91.4)
Ethnicity: Not Hispanic or Latino	48 4.466 (15149)	614 4.300 (15220)	92.5 (89.9, 94.5)
Ethnicity: Not reported	1 0.032 (104)	0 0.034 (109)	-∞ (NA, NA)
Race: American Indian or Alaska native	0 0.043 (196)	3 0.038 (180)	100.0 (-116.0, 100.0)
Race: Asian	3 0.258 (907)	24 0.247 (896)	88.0 (60.6, 97.7)
Race: Black or African American	4 0.602 (1909)	49 0.591 (1928)	92.0 (78.1, 97.9)
Race: Native Hawaiian or other Pacific Islander	0 0.016 (54)	1 0.008 (31)	100.0 (-1947.9, 100.0)

Table.J Subgroup Analyses of Updated Second Primary Endpoint: First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup, Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy Population, 16 Years and Older (Data Cutoff March 13, 2021)

Efficacy Endpoint Subgroup	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=21047) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Group (as Randomized) Placebo (N[a]=21210) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy (%) (95% CI[e])
Race: White	69 5.234 (16846)	749 5.054 (16952)	91.1 (88.6, 93.2)
Race: Multiracial	5 0.160 (538)	22 0.140 (503)	80.1 (46.1, 94.1)
Race: Not reported	0 0.027 (83)	6 0.031 (105)	100.0 (1.4, 100.0)
Baseline SARS-CoV-2 Status:Positive[h]	3 0.183 (593)	6 0.195 (643)	46.7 (-149.5, 91.4)
Baseline SARS-CoV-2 Status:Negative[i]	77 6.119 (19805)	846 5.883 (19838)	91.2 (88.9, 93.2)
Baseline SARS-CoV-2 Status:Unknown	1 0.038 (135)	2 0.033 (114)	56.9 (-728.5, 99.3)
Country: Argentina	16 1.033 (2655)	110 1.017 (2670)	85.7 (75.7, 92.1)

Table.J Subgroup Analyses of Updated Second Primary Endpoint: First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup, Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy Population, 16 Years and Older (Data Cutoff March 13, 2021)

Efficacy Endpoint Subgroup	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=21047) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Group (as Randomized) Placebo (N[a]=21210) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy (%) (95% CI[e])
Country: Brazil	14 0.441 (1419)	82 0.408 (1401)	84.2 (71.9, 91.7)
Country: Germany	0 0.047 (237)	1 0.048 (243)	100.0 (-3868.6, 100.0)
Country: South Africa	0 0.099 (358)	10 0.096 (358)	100.0 (56.6, 100.0)
Country: Turkey	0 0.029 (238)	6 0.026 (232)	100.0 (22.2, 100.0)
Country: United States	51 4.692 (15626)	645 4.515 (15691)	92.4 (89.9, 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.

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.

Table.J Subgroup Analyses of Updated Second Primary Endpoint: First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup, Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy Population, 16 Years and Older (Data Cutoff March 13, 2021)

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

f. Includes subjects who had at least one of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥30 kg/m^2).
g. Subjects (≥16 Years of age) who had BMI ≥30 kg/m^2.
h. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
i. Negative N-binding antibody result and negative NAAT result at Visit 1 and no medical history of COVID-19.

Table.K Demographic Characteristics, Participants 16 Years of Age and Older, With Protocol-Defined Case (Without Evidence of Infection Prior to 7 Days After Dose 2) (Data Cutoff March 13, 2021)

	Vaccine Group (as Randomized)		
Characteristic	**BNT162b2 (30 µg) (N[a]=77) n[b] (%)**	**Placebo (N[a]=833) n[b] (%)**	**Total (N[a]=910) n[b] (%)**
Age at Vaccination: Mean years (SD)	46.9 (14.79)	47.1 (15.58)	47.1 (15.51)
Age at Vaccination: Median (years)	50.0	47.0	48.0
Age at Vaccination: Min, max (years)	(19, 77)	(16, 88)	(16, 88)
Age Group: 16 to <18 years	0	10 (1.2)	10 (1.1)
Age Group: 18 to <65 years	70 (90.9)	699 (83.9)	769 (84.5)
Age Group: ≥65 years	7 (9.1)	124 (14.9)	131 (14.4)
Age Group: ≥65 to <75 years	6 (7.8)	98 (11.8)	104 (11.4)
Age Group: ≥75 years	1 (1.3)	26 (3.1)	27 (3.0)
Race: American Indian or Alaska Native	0	3 (0.4)	3 (0.3)
Race: Asian	3 (3.9)	23 (2.8)	26 (2.9)
Race: Black or African American	4 (5.2)	48 (5.8)	52 (5.7)
Race: Native Hawaiian or Other Pacific Islander	0	1 (0.1)	1 (0.1)
Race: White	67 (87.0)	730 (87.6)	797 (87.6)
Race: Multiracial	3 (3.9)	22 (2.6)	25 (2.7)
Race: Not reported	0	6 (0.7)	6 (0.7)
Sex: Female	35 (45.5)	444 (53.3)	479 (52.6)
Sex: Male	42 (54.5)	389 (46.7)	431 (47.4)
Ethnicity: Hispanic or Latino	29 (37.7)	236 (28.3)	265 (29.1)

Table.K Demographic Characteristics, Participants 16 Years of Age and Older, With Protocol-Defined Case (Without Evidence of Infection Prior to 7 Days After Dose 2) (Data Cutoff March 13, 2021)

Characteristic	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=77) n[b] (%)	Placebo (N[a]=833) n[b] (%)	Total (N[a]=910) n[b] (%)
Ethnicity: Not Hispanic or Latino	47 (61.0)	597 (71.7)	644 (70.8)
Ethnicity: Not reported	1 (1.3)	0	1 (0.1)
Comorbidities: Yes[c]	35 (45.5)	395 (47.4)	430 (47.3)
Comorbidities: No	42 (54.5)	438 (52.6)	480 (52.7)
Obesity: Yes[d]	27 (35.1)	310 (37.2)	337 (37.0)
Obesity: No	50 (64.9)	523 (62.8)	573 (63.0)
Country: Argentina	15 (19.5)	108 (13.0)	123 (13.5)
Country: Brazil	12 (15.6)	80 (9.6)	92 (10.1)
Country: Germany	0	1 (0.1)	1 (0.1)
Country: South Africa	0	9 (1.1)	9 (1.0)
Country: Turkey	0	5 (0.6)	5 (0.5)
Country: United States	50 (64.9)	630 (75.6)	680 (74.7)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2.
d. Subjects who had BMI ≥30 kg/m^2.

Table.L Updated Vaccine Efficacy: First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status, Among Participants Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy Population. Participants 16 Years of Age and Older (Data Cutoff March 13, 2021)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=19993)	Placebo (N[a]=20118)	
Efficacy Endpoint Subgroup	**Cases n1[b] Surveillance Time[c] (n2[d])**	**Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy (%) (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)
Comorbidity			
No comorbidity	42 3.329 (10757)	438 3.207 (10808)	90.8 (87.3, 93.4)
Any comorbidity[f]	35 2.763 (8954)	395 2.650 (8933)	91.5 (88.0, 94.2)
Any malignancy	3 0.228 (770)	27 0.213 (747)	89.6 (66.3, 98.0)
Cardiovascular	3 0.172 (584)	22 0.159 (555)	87.4 (58.1, 97.6)

Table.L Updated Vaccine Efficacy: First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status, Among Participants Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy Population. Participants 16 Years of Age and Older (Data Cutoff March 13, 2021)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=19993)	Placebo (N[a]=20118)	
Efficacy Endpoint Subgroup	Cases n1[b] Surveillance Time[c] (n2[d])	Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy (%) (95% CI[e])
Chronic pulmonary disease	8 0.474 (1582)	66 0.443 (1562)	88.7 (76.3, 95.3)
Diabetes	9 0.465 (1528)	60 0.444 (1513)	85.7 (70.9, 93.7)
Obese (≥30.0 kg/m^2)	27 2.083 (6673)	310 2.034 (6770)	91.5 (87.4, 94.5)
Hypertension	15 1.481 (4900)	190 1.427 (4895)	92.4 (87.1, 95.8)
Diabetes (including gestational diabetes)	9 0.468 (1537)	62 0.447 (1527)	86.1 (71.9, 93.9)

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.

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.

Table.L Updated Vaccine Efficacy: First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status, Among Participants Without Evidence of Infection Prior to 7 Days After Dose 2, Evaluable Efficacy Population. Participants 16 Years of Age and Older (Data Cutoff March 13, 2021)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=19993)	**Placebo (N^a=20118)**	
Efficacy Endpoint Subgroup	**Cases n1[b] Surveillance Time[c] (n2[d])**	**Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy (%) (95% CI[e])**

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. Subject who had 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2.

Table.M First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Participants 16 Years of Age and Older – Evaluable Efficacy Population (Data Cutoff March 13, 2021)

Secondary Efficacy Endpoint	BNT162b2 (N[a]=19993) Cases n1[b] Surveillance Time[c] (n2[d])	Placebo (N[a]=20118) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
First severe COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection	1 6.103 (19711)	21 5.971 (19741)	95.3 (71.0, 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.

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.

Table.N First Severe COVID-19 Occurrence After Dose 1 – Participants 16 Years of Age and Older – Dose 1 All-Available Efficacy Population (Data Cutoff March 13, 2021)

Secondary Efficacy Endpoint	BNT162b2 (N[a]=21909) Cases n1[b] Surveillance Time[c] (n2[d])	Placebo (N[a]=21908) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
First severe case occurrence after Dose 1	1 8.181 (21385)	30 8.032 (21316)	96.7 (80.3, 99.9)
After Dose 1 to before Dose 2	0 1.285 (21385)	6 1.293 (21316)	100.0 (14.6, 100.0)
Dose 2 to 7 days after Dose 2	0 0.403 (21056)	1 0.402 (20962)	100.0 (-3783.8, 100.0)
≥7 Days after Dose 2	1 6.493 (21029)	23 6.337 (20940)	95.8 (73.9, 99.9)

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 Dose 1 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.

Table.O Primary Efficacy Endpoint – Participants 16 Years of Age and Older – Dose 1 All-Available Efficacy Population (Data Cutoff March 13, 2021)

Efficacy Endpoint Subgroup	BNT162b2 (N[a]=21909) Cases n1[b] Surveillance Time[c] (n2[d])	Placebo (N[a]=21908) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
First COVID-19 occurrence after Dose 1	128 8.155 (21385)	998 7.874 (21315)	87.6 (85.1, 89.8)
After Dose 1 to before Dose 2	43 1.273 (21385)	98 1.266 (21315)	56.4 (37.0, 70.3)
Dose 2 to 7 days after Dose 2	3 0.403 (21049)	30 0.401 (20952)	90.0 (68.0, 98.1)
≥7 Days after Dose 2	82 6.479 (21019)	870 6.207 (20901)	91.0 (88.7, 92.9)

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 Dose 1 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.