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Ethical Conduct of the Study

The trial was conducted in accordance with the protocol, the ethical principles derived from international guidelines including the International Council for Harmonisation Good Clinical Practice Guidelines, the Declaration of Helsinki and Council for International Organizations of Medical Sciences International Ethical Guidelines, and applicable laws and regulations (including applicable privacy laws). An independent data monitoring committee reviewed efficacy and unblinded safety data. Institutional Review Board or Ethics Committee approval was obtained for each site prior to enrollment of any study participant.

The list of Institutional Review Board Committees is summarized at the end of this Supplementary Appendix.

Study Responsibilities

Pfizer was responsible for the design, study conduct, data collection, data analysis, data interpretation, and writing of this manuscript. Both Pfizer and BioNTech manufactured clinical trial material. BioNTech was the sponsor of the study and contributed to data interpretation and writing of the manuscript. All study data were available to all authors who vouch for its accuracy and adherence of the study to the protocol.

Testing for SARS-CoV-2 Virus and Antibodies

Testing for SARS-CoV-2 virus was conducted using the Cepheid Xpert Xpress SARS-CoV-2 RT-PCR test. Testing for SARS-CoV-2 antibodies was conducted using the Roche Elecsys[®] Anti-SARS-CoV-2 antibody test.

Determination of SARS-CoV-2 Lineage

For determination of SARS-CoV-2 lineage, nucleic acid extraction of midturbinate swab specimens was performed using the MagMAX[™] Viral/Pathogen Ultra Nucleic Acid Isolation Kit processed on a KingFisher[™] Presto.

SARS-CoV-2 viral genome sequencing was performed using the Ion Torrent and Illumina NextSeq platforms. For the Ion Torrent sequencing platform, the Ion AmpliSeq[™] SARS-CoV-2 Research Panel was used, which consists of 2 primer pools targeting a total of 237 PCR amplicons specific to SARS-CoV-2 and 5 human expression controls in each pool. Oligonucleotide primers based on available SARS-CoV-2 nucleotide sequences direct the amplification of the viral genome with amplicon lengths of 125–275 bp. The panel provides >99% coverage of the SARS-CoV-2 genome (~30 kb). To determine the optimal number of target amplification cycles, SARS-CoV-2 viral RNA content in the nucleic acid purified from the midturbinate specimens was quantified using the TaqMan[™] 2019-nCoV Assay Kit v1, the TaqMan[™] 2019-nCoV Control Kit v1, and TaqPath[™] 1-Step RT-qPCR Master Mix, CG. cDNA was synthesized with the SuperScript VILO cDNA synthesis kit. Libraries were prepared using the Ion AmpliSeq[™] Library Kit plus the Ion AmpliSeq[™] SARS-CoV-2 Research Panel according to the

manufacturer's instructions (ThermoFisher. Ion AmpliSeq™ Library Kit Plus USER GUIDE. Publication MAN0017003 version C.0.). Libraries underwent template preparation with Ion Chef according to the manufacturer's instructions. Prepared templates were loaded onto an Ion 530 chip for semiconductor sequencing on the Ion GeneStudio™ S5 plus sequencer according to the manufacturer's instructions. Raw sequencing reads generated by the Ion Torrent sequencer were quality and adaptor trimmed by Ion Torrent Suite and the resulting reads were then mapped to the complete genome of the SARS-CoV-2 Wuhan-Hu-1 isolate (GenBank accession number MN908947.3) using TMAP 5.14.0. Variant calling was carried out with the Torrent Variant Caller using the BAM file from the mapping of the cleaned sequence reads onto the reference sequence of SARS-CoV-2.

SARS-CoV-2 viral genome sequencing performed using the Illumina NextSeq platform used the AmpliSeq for Illumina SARS-CoV-2 panel of PCR primers to enrich for SARS-CoV-2 in the biological specimen. This was a 2-pool design, containing a total of 237 SARS-CoV-2 amplicon/primer pairs plus 5 human expression controls in each pool. Oligonucleotide primers based on available SARS-CoV-2 nucleotide sequences directed the amplification of overlapping amplicons with lengths of 125–275 bp that cover >99% of the viral genome. Nucleic acid extracted from the midturbinate specimens was digested initially with DNase (Invitrogen TURBO DNA-free™ Kit, AM1907), and RNA was purified using MagMAX™ beads before cDNA synthesis. Synthesis of cDNA using random sequence primers and downstream steps were as described by the manufacturer. SARS-CoV-2 amplicons were generated from the cDNA, followed by ligation of Universal Next Generation Sequencing Adaptors to the ends of the amplicons. Amplicon libraries were purified with magnetic beads and loaded onto a flow cell for sequence determination using the Illumina NextSeq instrument, according to the manufacturer's instructions. Sequences with ≥ 30 -fold coverage across the entire spike gene were advanced for viral lineage assignment. Single nucleotide variants were called using the “Low Frequency Variant Detection” function with the cut-off for sequence heterogeneity set at >10%.

SARS-CoV-2 lineage assignment was based on Pangolin 2.0 software, which runs a multinomial logistic regression model trained against lineage assignments based on isolate data from the Global Initiative on Sharing All Influenza Data (GISAID), a global science initiative established in 2008 that provides open-access to genomics data of influenza virus and SARS-CoV-2.

Definitions of Confirmed and Severe COVID-19 Cases

The definition of SARS-CoV-2-related cases was the presence of ≥ 1 of the following symptoms and SARS-CoV-2-NAAT positivity during or within 4 days before or after the symptomatic period: fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhea, and/or vomiting. The onset date of the case was the date that symptoms were first experienced by the participant. If new symptoms were reported ≤ 4 days after resolution of all previous symptoms, they were considered part of a single illness.

Confirmed severe COVID-19 required confirmation of COVID-19 and the presence of ≥ 1 of the following: clinical signs at rest indicative of severe systemic illness (respiratory rate ≥ 30 breaths per minute, heart rate ≥ 125 beats per minute, $SpO_2 \leq 93\%$ on room air at sea level, or $PaO_2/FiO_2 < 300$ mmHg); respiratory failure (defined as needing high-flow oxygen, non-invasive ventilation, mechanical ventilation, or extracorporeal membrane oxygenation); evidence of shock (systolic blood pressure < 90 mmHg, diastolic blood pressure < 60 mmHg, or requiring vasopressors); significant acute renal, hepatic,

or neurologic dysfunction; intensive care unit admission; and/or death
(<https://www.fda.gov/media/137926/download>).

Figure/Table Number	Figure/Table Title	Population(s)/Sample Size	Explanation
Figure 1	Disposition of Participants	All enrolled safety population ≥ 16 years of age N=44,165	Per protocol
Figure 2	Local Reactions and Systemic Events Reported within 7 Days after Receipt of BNT162b2 or Placebo by Baseline SARS-CoV-2 Status	Reactogenicity subset of participants ≥ 16 years of age (ie, participants who used an electronic diary for reporting local reactions and systemic events) N=9839	Per protocol
Figure 3	Efficacy of BNT162b2 against COVID-19 Occurrence after Dose 1 During the Placebo-controlled Follow-up Period	N=46,077 (all available)	All randomized participants ≥ 12 years of age
Table 1	Demographics	Participants ≥ 16 years of age N=44,047	Includes HIV-infected individuals
Table 2	Vaccine Efficacy against COVID-19 from 7 Days after Dose 2 During the Blinded Placebo Controlled Follow-up Period (Evaluable Efficacy Population, ≥ 12 Years Old)	a. Efficacy endpoint including individuals without evidence of prior infection (N=42,094) b. Efficacy endpoint including individuals with and those without evidence of prior infection (N=44,486)	Evaluable population: <ul style="list-style-type: none"> received 2 vaccinations as randomized no major protocol deviations Excludes HIV+ participants
Table 3	Vaccine Efficacy Overall and by Subgroup in Participants Without Evidence of Infection Prior to 7 Days After Dose 2 During the Blinded Placebo Controlled Follow-up Period	N=42,094 (same as efficacy endpoint in Table 2, participants ≥ 12 years of age)	
Table S2	Baseline Comorbidities in Participants ≥ 16 Years of Age	N=44,047	Includes HIV-infected individuals
Table S3	Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 During the Blinded Follow-up Period	Participants ≥ 16 years of age N=43,847	Vaccinated minus 200 HIV-infected participants
Table S4	Causes of Death from Dose 1 to Unblinding (Safety Population, ≥ 16 Years Old)	Participants ≥ 16 years of age N=43,847	Vaccinated minus 200 HIV-infected participants
Table S5	Vaccine Efficacy Overall and by Subgroup after Dose 1 During the Blinded Placebo Controlled Follow-up Period (All-Available Population)	N=46,077 (all available)	
Table S6	Vaccine Efficacy against Severe COVID-19 Occurrence after Dose 1 (All-Available Population)	N=46,077 (all available, participants ≥ 12 years of age)	
Table S7	Vaccine Efficacy from 7 Days after Dose 2 by Underlying Comorbidities (Risk Status) among Participants without Evidence of Infection Prior to 7 Days after Dose 2 (Evaluable Efficacy Population)	N=42,094 (same as efficacy endpoint in Table 2, participants ≥ 12 years of age)	

Table S1 | Explanation of the Changes in Denominator Numbers in Various Analyses.

Charlson Comorbidity Index Category	BNT162b2 (N ^a =22,026)	Placebo (N ^a =22,021)	Total (N ^a =44,047)
	n ^b (%)	n ^b (%)	n ^b (%)
Participants with any Charlson comorbidity	4628 (21.0)	4511 (20.5)	9139 (20.7)
AIDS/HIV	100 (0.5)	100 (0.5)	200 (0.5)
Any malignancy	812 (3.7)	757 (3.4)	1569 (3.6)
Cerebrovascular disease	227 (1.0)	198 (0.9)	425 (1.0)
Chronic pulmonary disease	1783 (8.1)	1775 (8.1)	3558 (8.1)
Congestive heart failure	109 (0.5)	102 (0.5)	211 (0.5)
Dementia	7 (0.0)	11 (0.0)	18 (0.0)
Diabetes with chronic complication	116 (0.5)	130 (0.6)	246 (0.6)
Diabetes without chronic complication	1700 (7.7)	1699 (7.7)	3399 (7.7)
Hemiplegia or paraplegia	15 (0.1)	25 (0.1)	40 (0.1)
Leukemia	14 (0.1)	11 (0.0)	25 (0.1)
Lymphoma	26 (0.1)	36 (0.2)	62 (0.1)
Metastatic solid tumor	4 (0.0)	3 (0.0)	7 (0.0)
Mild liver disease	152 (0.7)	115 (0.5)	267 (0.6)
Moderate or severe liver disease	2 (0.0)	3 (0.0)	5 (0.0)
Myocardial infarction	225 (1.0)	218 (1.0)	443 (1.0)
Peptic ulcer disease	63 (0.3)	84 (0.4)	147 (0.3)
Peripheral vascular disease	144 (0.7)	139 (0.6)	283 (0.6)
Renal disease	140 (0.6)	153 (0.7)	293 (0.7)
Rheumatic disease	75 (0.3)	71 (0.3)	146 (0.3)

Table S2 | Baseline Comorbidities in Participants ≥ 16 Years of Age. Baseline comorbid conditions are classified according to the Charlson Comorbidity Index (Charlson M, Szatrowski TP, Peterson J, Gold J. Validation of a combined comorbidity index. *J Clin Epidemiol* 1994;47:1245-51.). a. N=number of participants in the specified group. This value is the denominator for the percentage calculations. b. n=number of participants with the specified characteristic. Participants with multiple occurrences within each category are counted only once. For ‘Participants with any Charlson comorbidity’, n=number of participants reporting ≥ 1 occurrence of any Charlson comorbidity.

Adverse Event	BNT162b2 (N^a=21,926) n^b (%)	Placebo (N^a=21,921) n^b (%)
Any event	6617 (30.2)	3048 (13.9)
Related ^c	5241 (23.9)	1311 (6.0)
Severe	262 (1.2)	150 (0.7)
Life-threatening	21 (0.1)	26 (0.1)
Any serious adverse event	127 (0.6)	116 (0.5)
Related ^{c,d}	3 (0.0)	0
Severe	71 (0.3)	66 (0.3)
Life-threatening	21 (0.1)	26 (0.1)
Any adverse event leading to withdrawal	32 (0.1)	36 (0.2)
Related ^c	13 (0.1)	11 (0.1)
Severe	10 (0.0)	10 (0.0)
Life-threatening	3 (0.0)	7 (0.0)
Death	3 (0.0)	5 (0.0)

Table S3 | Participants Reporting at Least 1 Adverse Event from Dose 1 to 1 Month After Dose 2 During the Blinded Follow-up Period. The population included all ≥ 16 -year-old participants who received ≥ 1 dose of vaccine irrespective of follow-up time. a. N=number of participants in the specified group. This value is the denominator for the percentage calculations. b. n=Number of participants reporting ≥ 1 occurrence of the specified event category. For ‘any event’, n=number of participants reporting ≥ 1 occurrence of any event. c. Assessed by the investigator as related to investigational product. d. Shoulder injury related to vaccine administration, right axillary lymphadenopathy, and paroxysmal ventricular arrhythmia (as previously reported). Adverse events for 12–15-year-old participants were reported previously.¹¹

Reported Cause of Death ^a	BNT162b2 (N=21,926)	Placebo (N=21,921)
	n	n
Deaths	15	14
Acute respiratory failure	0	1
Aortic rupture	0	1
Arteriosclerosis	2	0
Biliary cancer metastatic	0	1
COVID-19	0	2
COVID-19 pneumonia	1	0
Cardiac arrest	4	1
Cardiac failure congestive	1	0
Cardiorespiratory arrest	1	1
Chronic obstructive pulmonary disease	1	0
Death	0	1
Dementia	0	1
Emphysematous cholecystitis	1	0
Hemorrhagic stroke	0	1
Hypertensive heart disease	1	0
Lung cancer metastatic	1	0
Metastases to liver	0	1
Missing	0	1
Multiple organ dysfunction syndrome	0	2
Myocardial infarction	0	2
Overdose	0	1
Pneumonia	0	2
Sepsis	1	0
Septic shock	1	0
<i>Shigella</i> sepsis	1	0
Unevaluable event	1	0

Table S4 | Causes of Death from Dose 1 to Unblinding (Safety Population, ≥16 Years Old). a. Multiple causes of death could be reported for each participant. There were no deaths among 12–15-year-old participants.

First COVID-19 Occurrence after Dose 1	BNT162b2 (N ^a =23,040)		Placebo (N ^a =23,037)		VE (%)	(95% CI ^e)
	n1 ^b	Surveillance Time ^c (n2 ^d)	n1 ^b	Surveillance Time ^c (n2 ^d)		
Overall (≥12 years old)	131	8.412 (22,505)	1034	8.124 (22,434)	87.8	(85.3, 89.9)
Efficacy endpoint by subgroup						
Select age groups (years)						
16 to 17	3	0.094 (373)	19	0.090 (370)	84.8	(48.4, 97.1)
16 to 55	95	4.845 (12,645)	693	4.669 (12,626)	86.8	(83.6, 89.5)
>55	33	3.310 (8740)	306	3.204 (8689)	89.6	(85.0, 92.9)
≥65	12	1.645 (4455)	138	1.596 (4437)	91.6	(84.8, 95.7)
≥75	2	0.326 (905)	26	0.310 (877)	92.7	(70.7, 99.2)
Sex						
Male	70	4.355 (11,560)	500	4.115 (11,312)	86.8	(83.0, 89.9)
Female	61	4.057 (10,945)	534	4.009 (11,122)	88.7	(85.3, 91.5)
Race						
White	115	6.957 (18,538)	916	6.719 (18,479)	87.9	(85.3, 90.1)
Black or African American	6	0.783 (2042)	53	0.770 (2063)	88.9	(74.1, 96.1)
American Indian or Alaska Native	1	0.061 (216)	7	0.055 (209)	86.9	(-1.6, 99.7)
Asian	4	0.348 (995)	26	0.337 (990)	85.1	(57.0, 96.2)
Native Hawaiian or other Pacific Islander	0	0.021 (58)	1	0.011 (32)	100.0	(-2000.0, 100.0)
Multiracial	5	0.208 (565)	25	0.190 (546)	81.8	(51.6, 94.6)
Not reported	0	0.035 (91)	6	0.042 (115)	100.0	(-0.7, 100.0)
Ethnicity						
Hispanic/Latinx	52	2.351 (5701)	302	2.282 (5673)	83.3	(77.5, 87.8)
Non-Hispanic/non-Latinx	78	6.018 (16,692)	730	5.799 (16,647)	89.7	(87.0, 92.0)
Not reported	1	0.043 (112)	2	0.043 (114)	49.4	(-872.9, 99.1)
Country						
Argentina	32	1.282 (2846)	146	1.269 (2840)	78.3	(68.0, 85.7)
Brazil	14	0.554 (1430)	95	0.520 (1420)	86.1	(75.6, 92.7)
Germany	2	0.067 (246)	1	0.069 (250)	-104.5	(-11,965.9, 89.4)
South Africa	0	0.128 (367)	11	0.125 (365)	100.0	(61.1, 100.0)
Turkey	3	0.048 (246)	12	0.045 (244)	76.4	(12.4, 95.7)
USA	80	6.333 (17,370)	769	6.095 (17,315)	90.0	(87.4, 92.1)
Baseline SARS-CoV-2 status						
Positive ^f	13	0.250 (692)	17	0.265 (736)	19.2	(-76.6, 63.9)
Positive N-binding only	2	0.192 (521)	7	0.198 (542)	70.5	(-54.7, 97.0)

Positive NAAT only	10	0.020 (66)	9	0.020 (69)	-10.5	(-207.3, 59.7)
Positive NAAT and N-binding	1	0.038 (105)	1	0.046 (124)	-20.5	(-9359.2, 98.5)
Negative ^g	116	8.101 (21,615)	1015	7.804 (21,521)	89.0	(86.6, 91.0)
Unknown	2	0.061 (198)	2	0.055 (177)	9.7	(-1145.4, 93.5)

Table S5 | Vaccine Efficacy Overall and by Subgroup after Dose 1 During the Blinded Placebo Controlled Follow-up Period (All-Available Population). Efficacy data are presented for participants ≥ 12 years old. a. N=number of participants in the specified group. b. n1=Number of participants meeting the endpoint definition. c. Total surveillance time in 1000 person-years for the given endpoint across all participants 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 participants at risk for the endpoint. e. CI for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time. f. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. g. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.

Efficacy Endpoint Subgroup	BNT162b2 (N ^a =23,040)		Placebo (N ^a =23,037)		VE (%)	(95% CI ^e)
	n1 ^b	Surveillance Time ^c (n2 ^d)	n1 ^b	Surveillance Time ^c (n2 ^d)		
First severe COVID-19 occurrence after dose 1	1	8.439 (22,505)	30	8.288 (22,435)	96.7	(80.3, 99.9)
After dose 1 to before dose 2	0	1.351 (22,505)	6	1.360 (22,435)	100.0	(14.5, 100.0)
Dose 2 to 7 days after dose 2	0	0.425 (22,170)	1	0.423 (22,070)	100.0	(-3783.5, 100.0)
≥7 Days after dose 2	1	6.663 (22,142)	23	6.505 (22,048)	95.7	(73.9, 99.9)

Table S6 | Vaccine Efficacy against Severe COVID-19 Occurrence after Dose 1 (All-Available Population). Efficacy data are presented for participants ≥12 years old. a. N=number of participants in the specified group. b. n1=number of participants meeting the endpoint definition. c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for severe COVID-19 case accrual is from dose 1 to the end of the surveillance period for the overall row, and from the start to the end of the range stated for each time interval. d. n2=number of participants at risk for the endpoint. e. CI for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time. Severe COVID-19 as defined by the US FDA [<https://www.fda.gov/media/137926/download>]).

Efficacy Endpoint Subgroup	BNT162b2 (N ^a =20,998)		Placebo (N ^a =21,096)		VE (%)	(95% CI ^e)
	n1 ^b	Surveillance Time ^c (n2 ^d)	n1 ^b	Surveillance Time ^c (n2 ^d)		
First COVID-19 occurrence from 7 days after dose 2						
Overall	77	6.247 (20,712)	850	6.003 (20,713)	91.3	(89.0, 93.2)
At risk ^f						
Yes	35	2.797 (9167)	401	2.681 (9136)	91.6	(88.2, 94.3)
No	42	3.450 (11,545)	449	3.322 (11,577)	91.0	(87.6, 93.6)
Age group (years) and at risk						
16–64 and at risk	29	2.083 (6632)	325	1.993 (6629)	91.5	(87.5, 94.4)
≥65 and at risk	6	0.680 (2322)	71	0.656 (2304)	91.8	(81.4, 97.1)
Obese ^g						
Yes	27	2.103 (6796)	314	2.050 (6875)	91.6	(87.6, 94.6)
No	50	4.143 (13,911)	536	3.952 (13,833)	91.1	(88.1, 93.5)
Age group (years) and obese						
16–64 and obese	24	1.680 (5303)	266	1.624 (5344)	91.3	(86.7, 94.5)
≥65 and obese	3	0.404 (1370)	45	0.410 (1426)	93.2	(78.9, 98.7)

Table S7 | Vaccine Efficacy from 7 Days after Dose 2 by Underlying Comorbidities (Risk Status) among Participants Without Evidence of Infection Prior to 7 Days after Dose 2 (Evaluable Efficacy Population). Efficacy data are presented for participants ≥12 years old. a. N=number of participants in the specified group. b. n1=number of participants meeting the endpoint definition. c. Total surveillance time in 1000 person-years for the given endpoint across all participants 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 participants at risk for the endpoint. e. CI for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time. f. Includes participants who had ≥1 Charlson Comorbidity Index (CMI) category or obesity (body mass index [BMI] ≥30 kg/m² [≥16 years old] or BMI ≥95th percentile [12–15 years old]). g. Participants who had BMI ≥30 kg/m² (≥16 years old) or BMI ≥95th percentile (12–15 years old; refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm).

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