C4591001 COVID-19 BLA Safety and Efficacy Data For ACIP

(Data Cutoff 13-Mar-2021)

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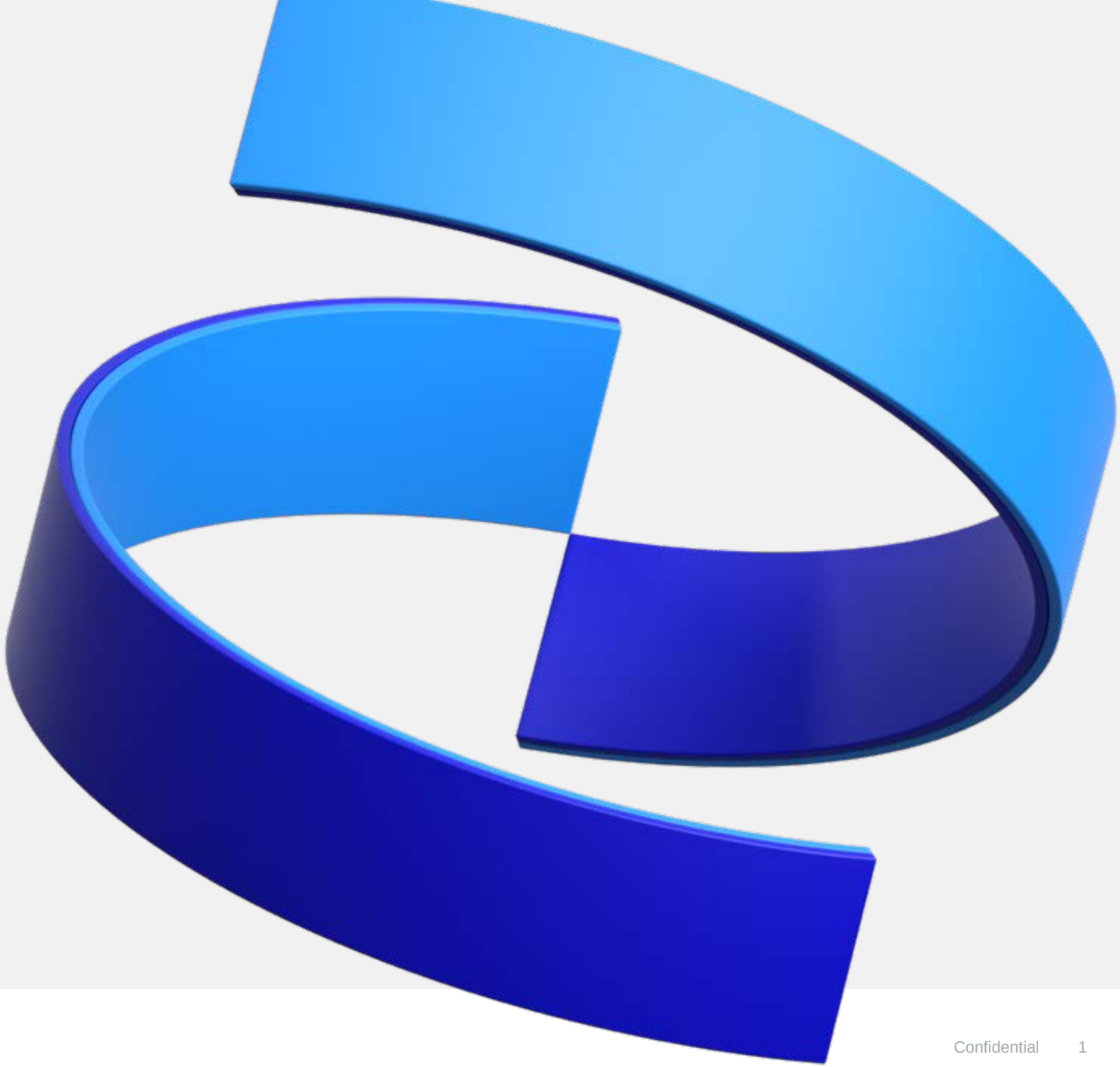


Agenda

1. High level overview of long-term safety analyses for individuals 16+ years of age
2. Adverse events of special interest
3. Efficacy update through 13-March-2021
4. Sequence data on COVID-19 cases through 13-March-2021
5. Pregnancy data through 13-March-2021

Not Covered in presentation but data available for:

HIV+ participants, SARS-CoV-2 +/- at baseline, more than 1 episode COVID-19 cases in placebo group, placebo participants who developed COVID-19 then received BNT162b2, booster data

Phase 2/3 Safety Schema – Started 27 July, 2020

Vaccination period | **Follow-up period**

Up to 2 years

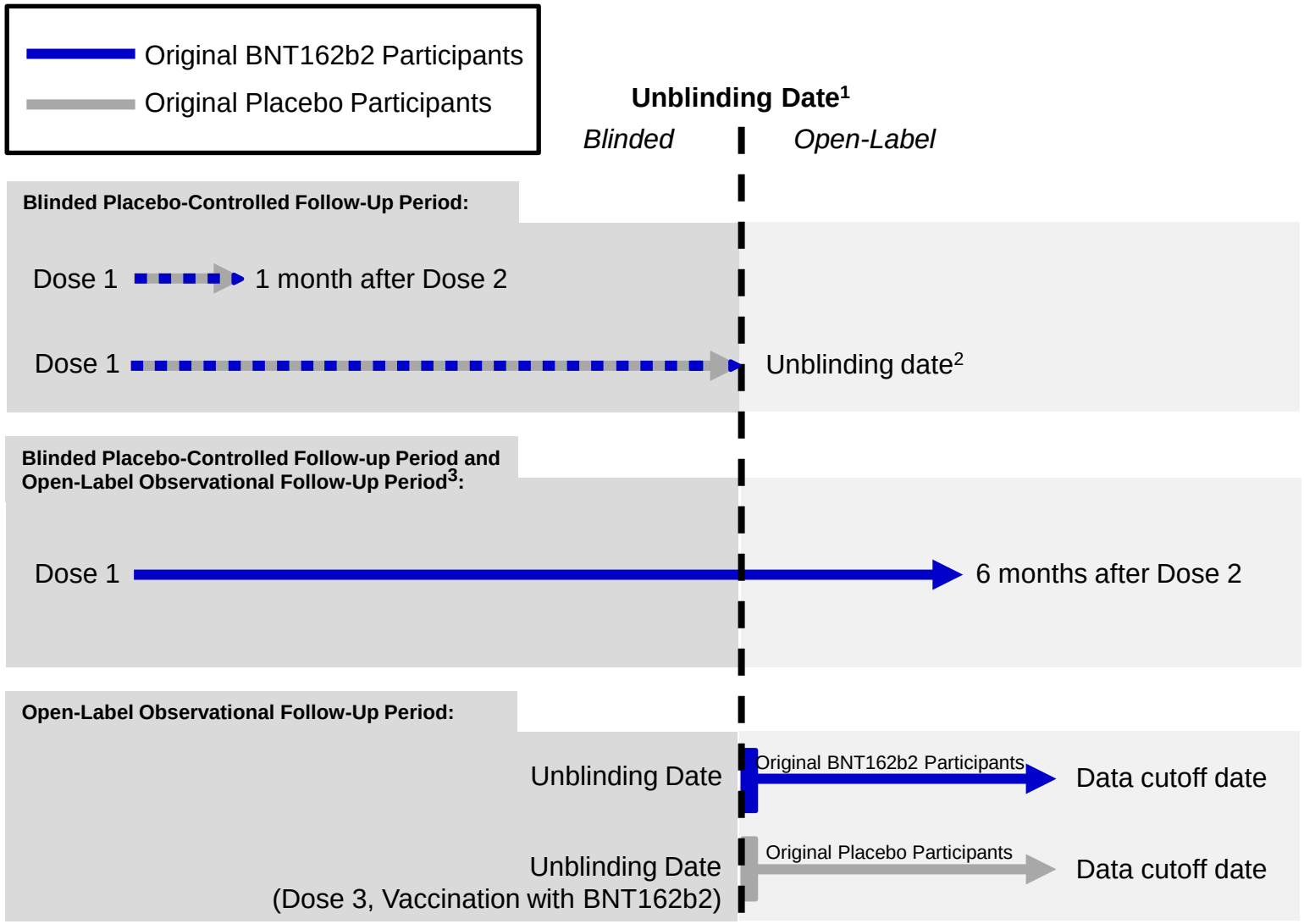
Active surveillance
for potential COVID-19 symptoms **TRIGGERING**
telehealth or in-person visit and nasal swab

7 days | **7 days** — **Reactogenicity in subsets for 16 and above; all 12-15 year olds**

One month post dose 2 — **Non-serious AE: all participants**

Six months post dose 2 — **Serious AE: all participants**

Through study — **Deaths: all participants**



[1] Will vary by participant. Adverse event data analyzed from Dose 1 to unblinding date (on or after 14 December 2020), or from unblinding date to data cutoff date, are reported as incidence rates adjusted for exposure time.
[2] Up to ~5 months after Dose 2.
[3] Cumulative BNT162b2 follow-up to at least 6 months after Dose 2, N~3000/age group (16 to 55 years of age, >55 years of age).

Follow-up Time After Dose 2: >16 year olds – Safety Population

trolled			
<2 Months	1251 (5.7)	1331 (6.0)	2582 (5.9)
≥2 Months to <4 months	7744 (35.2)	8070 (36.6)	15814 (35.9)
≥4 Months to <6 months	11253 (51.1)	11316 (51.4)	22569 (51.2)
≥6 Months	1778 (8.1)	1304 (5.9)	3082 (7.0)
Total exposure from Dose 2 to cutoff date			
<2 Months	390 (1.8)		
≥2 Months to <4 months	679 (3.1)		
≥4 Months to <6 months	8951 (40.6)		
≥6 Months	12006 (54.5)		

Demography for 16-55 and >55 year olds (Safety population)

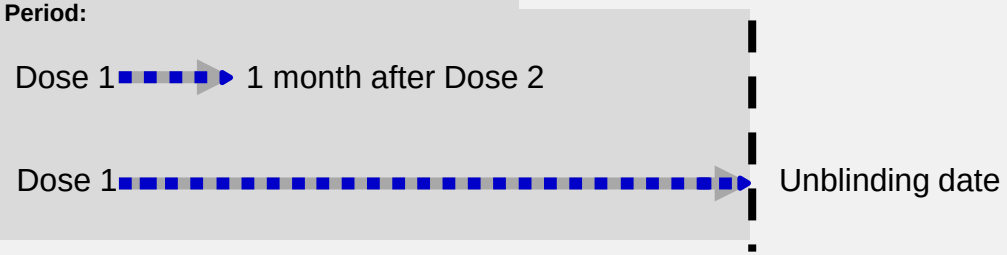
		BNT162b2		Placebo	
		16-55 Years (N=13069) n (%)	>55 Years (N=8957) n (%)	16-55 Years (N=13095) n (%)	>55 Years (N=8926) n (%)
Sex	Male	6640 (50.8)	4682 (52.3)	6412 (49.0)	4686 (52.5)
	Female	6429 (49.2)	4275 (47.7)	6683 (51.0)	4240 (47.5)
Race	White	10221 (78.2)	7835 (87.5)	10251 (78.3)	7813 (87.5)
	Black or African American	1429 (10.9)	669 (7.5)	1436 (11.0)	682 (7.6)
	American Indian or Alaska native	165 (1.3)	56 (0.6)	153 (1.2)	64 (0.7)
	Asian	703 (5.4)	249 (2.8)	712 (5.4)	230 (2.6)
	Native Hawaiian or other Pacific Islander	43 (0.3)	15 (0.2)	21 (0.2)	11 (0.1)
	Multiracial	437 (3.3)	113 (1.3)	438 (3.3)	95 (1.1)
	Not reported	71 (0.5)	20 (0.2)	84 (0.6)	31 (0.3)
Racial desig.	Japanese	39 (0.3)	39 (0.4)	41 (0.3)	37 (0.4)
Ethnicity	Hispanic/Latino	1657 (18.5)	604 (32.4)	4023 (30.7)	1672 (18.7)
	Non-Hispanic/non-Latino	7244 (80.9)	1259 (67.4)	9011 (68.8)	7201 (80.7)
	Not reported	56 (0.6)	4 (0.2)	61 (0.5)	53 (0.6)
Country	USA	9251 (70.8)	7541 (84.2)	9267 (70.8)	7527 (84.3)
	Others*	3818 (29.2)	1416 (15.8)	3828 (29.2)	1399 (15.7)

*Argentina, Brazil, Germany, South Africa, Turkey

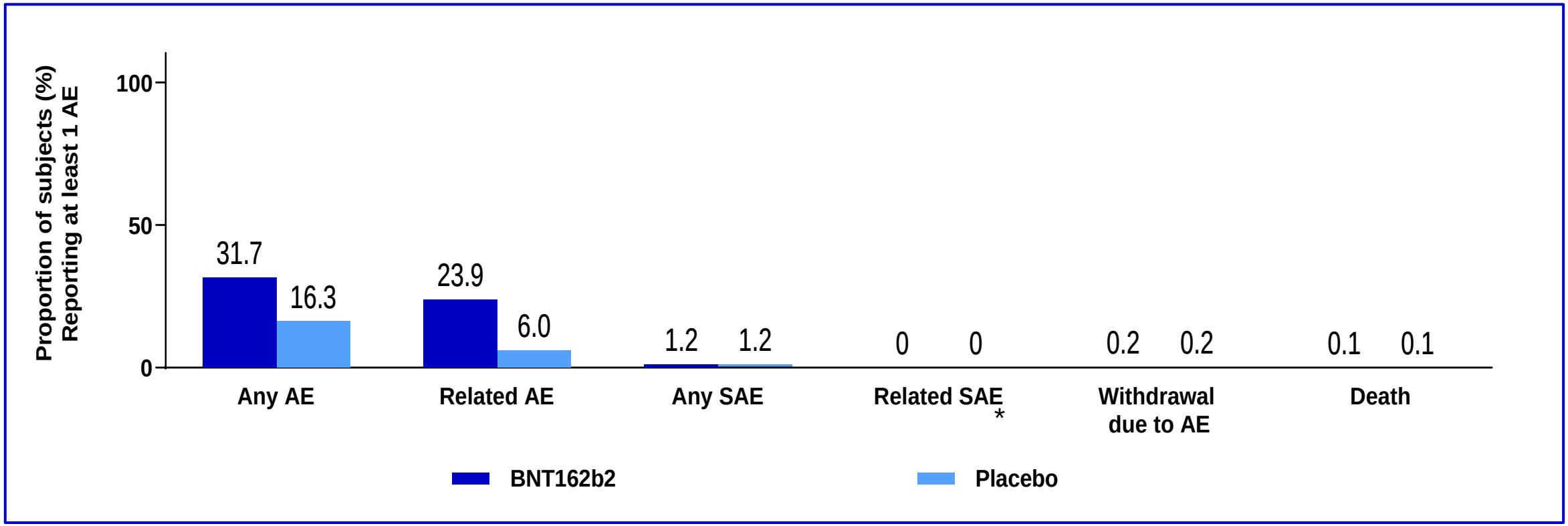
Safety

Adverse Events to the Unblinding Date

Blinded Placebo-Controlled Follow-Up Period:

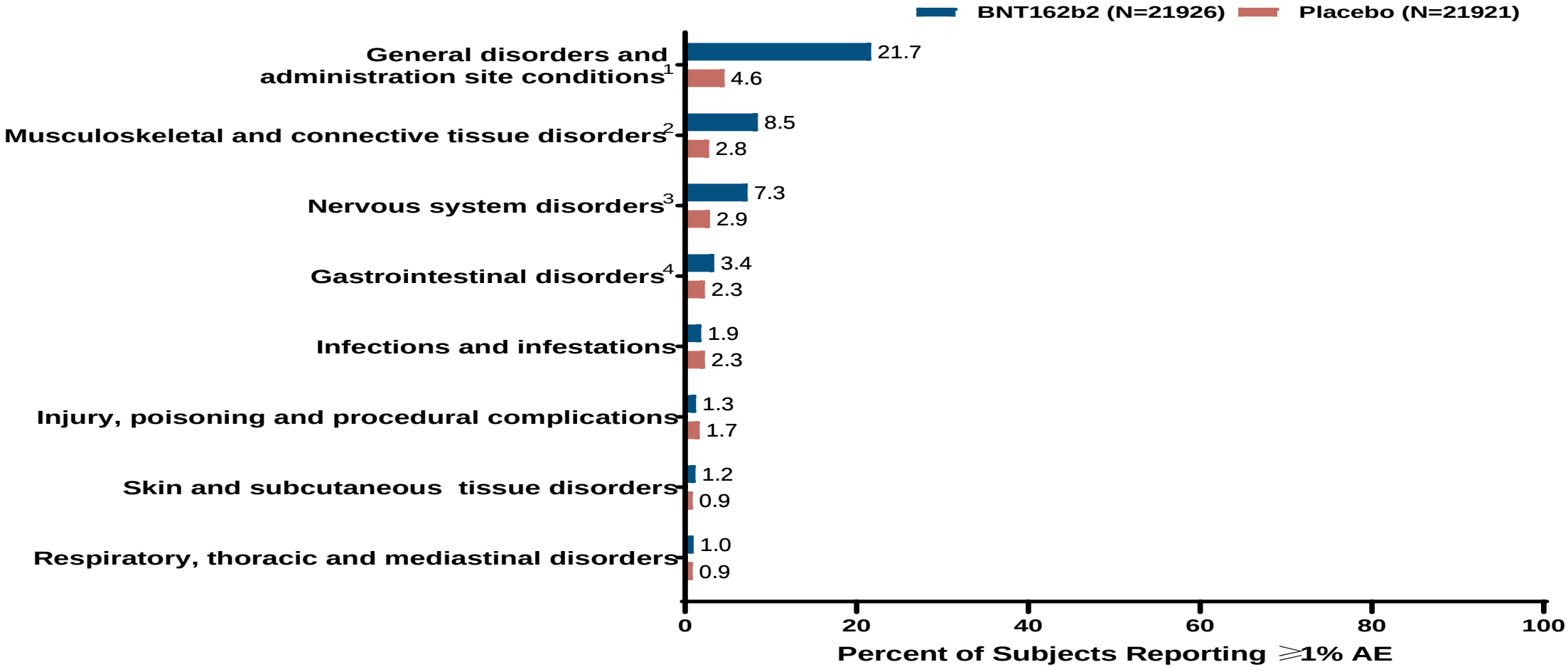


Overall Adverse Events from Dose 1 to Unblinding Date: ≥ 16 years of age (N=43,847)



*Related SAEs: 4 BNT162b2; 1 Placebo

Adverse Events ≥1.0% by System Organ Class From Dose 1 to Unblinding Date: ≥ 16 Years of Age



1. Predominantly reflect local reactions at the injection site and systemic reactions of fever and fatigue
2. Predominantly reflects arthralgia and myalgia
3. Predominantly reflects headache
4. Predominantly reflects nausea and diarrhea

Higher Frequency PTs Reported in the BNT162b2 7 Days after Dose 1 and 7 Days after Dose 2

These adverse events clustered within the 7 day period after each dose, and are considered to be attributable to experiencing the reactogenicity events, and plausibly associated with local reactions and systemic events

Preferred Terms*	Dose 1 to 1MPD2		7 days PD1		7 days PD2	
	BNT169b2 (N=21926) n; % (95% CI)	Placebo (N=21921) n; % (95% CI)	BNT169b2 (N=21926) n; % (95% CI)	Placebo (N=21921) n; % (95% CI)	BNT169b2 (N=21571) n; % (95% CI)	Placebo (N=21549) n; % (95% CI)
Pain in extremity	185; **0.8** (0.7, 1.0)	44; **0.2** (0.1, 0.3)	88; **0.4** (0.3, 0.5)	12; **0.1** (0.0, 0.1)	84; **0.4** (0.3, 0.5)	11; **0.1** (0.0, 0.1)
Malaise	130; **0.6** (0.5, 0.7)	22; **0.1** (0.1, 0.2)	48; **0.2** (0.2, 0.3)	9; **0.0** (0.0, 0.1)	88; **0.4** (0.3, 0.5)	10; **0.0** (0.0, 0.1)
Decreased appetite	39; **0.2** (0.1, 0.2)	9; **0.0** (0.0, 0.1)	10; **0.0** (0.0, 0.1)	6; **0.0** (0.0, 0.1)	28; **0.1** (0.1, 0.2)	3; **0.0** (0.0, 0.0)
Lethargy	25; **0.1** (0.1, 0.2)	6; **0.0** (0.0, 0.1)	10; **0.0** (0.0, 0.1)	5; **0.0** (0.0, 0.1)	18; **0.1** (0.0, 0.1)	1; **0.0** (0.0, 0.0)
Asthenia	76; **0.3** (0.3, 0.4)	25; **0.1** (0.1, 0.2)	23; **0.1** (0.1, 0.2)	9; **0.0** (0.0, 0.1)	51; **0.2** (0.2, 0.3)	9; **0.0** (0.0, 0.1)
Night sweats	17; **0.1** (0.0, 0.1)	3; **0.0** (0.0, 0.0)	3; **0.0** (0.0, 0.0)	0; **0.0** (0.0, 0.0)	13; **0.1** (0.0, 0.1)	1; **0.0** (0.0, 0.0)
Hyperhidrosis	31; **0.1** (0.1,0.2)	9; **0.0** (0.0, 0.1)	11; **0.1** (0.0, 0.1)	4; **0.0** (0.0, 0.0)	18; **0.1** (0.0, 0.1)	4; **0.0** (0.0, 0.0)

* Individual participants could report an adverse event more than once

Serious Adverse Events with Incidence Rates ≥0.1 by System Organ Class for ≥ 16 years of age: From Dose 1 to Unblinding Date

	BNT162b2 (30 µg)(N=21926)		Placebo (N=21921)	
System Organ Class	n	IR/100 PY	n	IR/100 PY
ANY EVENT	268	3.2	268	3.3
CARDIAC DISORDERS	42	0.5	39	0.5
EYE DISORDERS	5	0.1	3	0
GASTROINTESTINAL DISORDERS	23	0.3	21	0.3
GENERAL DISORDERS & ADMINISTRATION SITE CONDITIONS	10	0.1	4	0
HEPATOBILIARY DISORDERS	12	0.1	7	0.1
INFECTIONS AND INFESTATIONS	50	0.6	57	0.7
INJURY, POISONING, PROCEDURAL COMPLICATIONS	19	0.2	26	0.3
METABOLISM & NUTRITION DISORDERS	4	0	10	0.1
MUSCULOSKELETAL & CONNECTIVE TISSUE DISORDERS	13	0.2	11	0.1
NEOPLASMS BENIGN, MALIGNANT, UNSPECIFIED	39	0.5	35	0.4
NERVOUS SYSTEM DISORDERS	25	0.3	23	0.3
PREGNANCY, PUERPERIUM, PERINATAL CONDITIONS	2	0	6	0.1
PSYCHIATRIC DISORDERS	5	0.1	9	0.1
RENAL & URINARY DISORDERS	11	0.1	8	0.1
REPRODUCTIVE SYSTEM & BREAST DISORDERS	2	0	5	0.1
RESPIRATORY, THORACIC & MEDIASTINAL DISORDERS	14	0.2	14	0.2
VASCULAR DISORDERS	12	0.1	13	0.2

Related SAEs; ≥ 16 Years of Age From Dose 1 to Unblinding Date

Treatment	System Organ Class	Preferred Term	Dose	Rel Day	Duration Day	Toxicity Grade	Outcome*
BNT162b2	BLOOD AND LYMPHATIC SYSTEM DISORDERS	Lymphadenopathy (Rt axilla)	1	13	66	2	R
BNT162b2	CARDIAC DISORDERS	Ventricular arrhythmia	2	1	8	3	R
BNT162b2	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Shoulder injury related to vaccine administration	2	1	153	3	R
BNT162b2	NERVOUS SYSTEM DISORDERS	Paraesthesia (Rt leg)	2	47	Ongoing	2	RG
Placebo	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Psoriatic arthropathy	2	38	Ongoing	2	N

Rel Day = start date of AE relative to the last vaccination;

*R = recovered/resolved; RG = recovering/resolving N = not recovered/not resolved

Incidence Rates of Deaths from Dose 1 to Unblinding Date in Subjects ≥ 16 Years of Age: None Related

	BNT162b2 (30 µg) (N=21926, TE/100 PY=83.4)		Placebo (N=21921, TE/100 PY=82.2)	
Cause of death	**n**	**IR (/100 PY)**	**n**	**IR (/100 PY)**
All Deaths	15	0.2	14	0.2
Acute respiratory failure	0	0	1	0
Aortic rupture	0	0	1	0
Arteriosclerosis	2	0	0	0
Biliary cancer metastatic	0	0	1	0
COVID-19	0	0	2	0
COVID-19 pneumonia	1	0	0	0
Cardiac arrest	4	0	1	0
Cardiac failure congestive	1	0	0	0
Cardio-respiratory arrest	1	0	1	0
Chronic obstructive pulmonary disease	1	0	0	0
Death	0	0	1	0
Dementia	0	0	1	0
Emphysematous cholecystitis	1	0	0	0

TE = Total exposure time

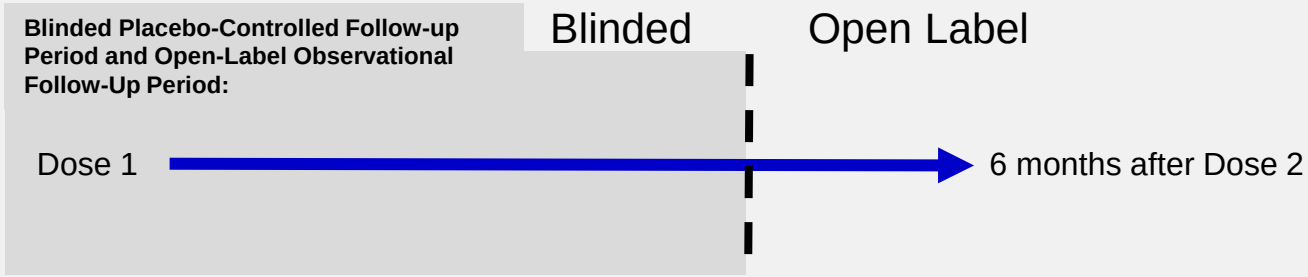
Incidence Rates of Deaths from Dose 1 to Unblinding date in Subjects ≥ 16 Years of Age: None Related (Cont.)

	BNT162b2 (30 µg) (N=21926, TE/100 PY=83.4)		Placebo (N=21921, TE/100PY=82.2)	
Cause of death	**n**	**IR (/100 PY)**	**n**	**IR (/100 PY)**
All Deaths	15	0.2	14	0.2
Haemorrhagic stroke	0	0	1	0
Hypertensive heart disease	1	0	0	0
Lung cancer metastatic	1	0	0	0
Metastases to liver	0	0	1	0
Missing	0	0	1	0
Multiple organ dysfunction syndrome	0	0	2	0
Myocardial infarction	0	0	2	0
Overdose	0	0	1	0
Pneumonia	0	0	2	0
Sepsis	1	0	0	0
Septic shock	1	0	0	0
Shigella sepsis	1	0	0	0
Unevaluable event	1	0	0	0

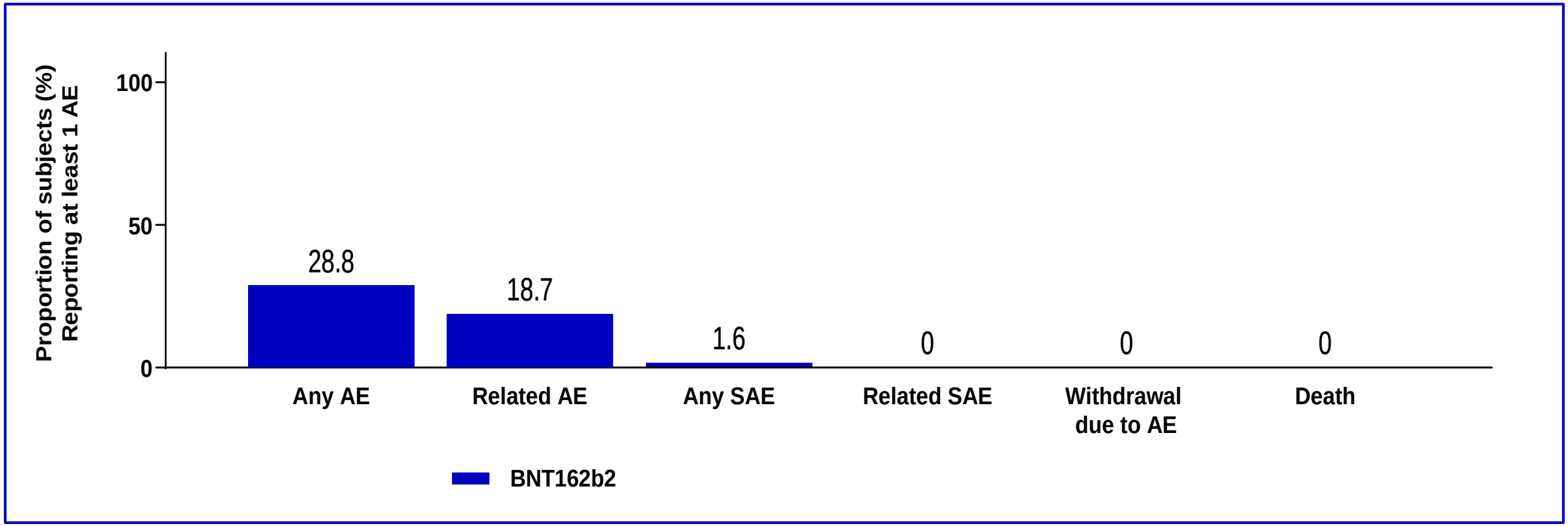
TE = Total exposure time

Safety

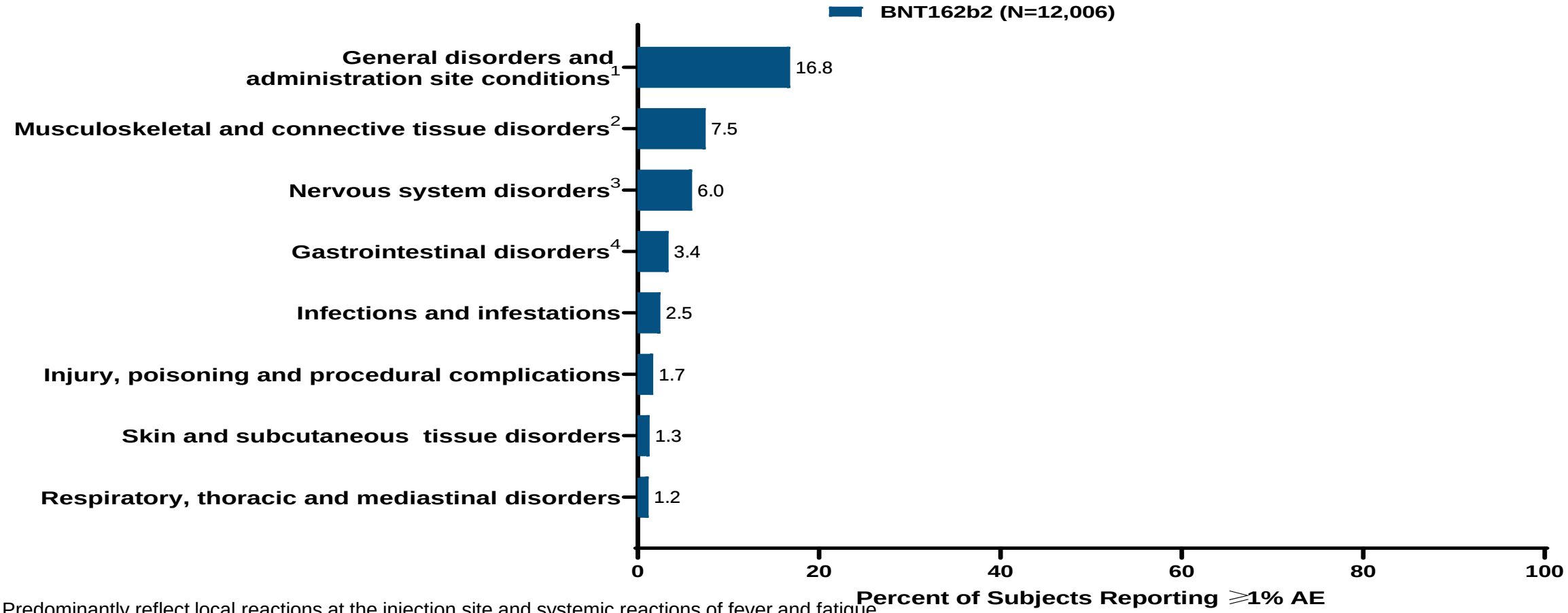
Adverse Events to the Data Cutoff: **Dose 1 to 6 Months after Dose 2 in BNT162b2 Recipients**



Overall Adverse Events from Dose 1 to 6 Months after Dose 2: ≥ 16 years of age in Subjects Who Originally Received BNT162b2 (N=12,006)



Adverse Events ≥1.0% by System Organ Class from Dose 1 to 6 Months after Dose 2: ≥ 16 years of age in Subjects Who Originally Received BNT162b2 (N=12,006)



1. Predominantly reflect local reactions at the injection site and systemic reactions of fever and fatigue
2. Predominantly reflects arthralgia and myalgia
3. Predominantly reflects headache
4. Predominantly reflects nausea and diarrhea

Serious Adverse Events ≥0.1% by System Organ Class from Dose 1 to 6 Months after Dose 2: ≥ 16 years of age in Subjects Who Originally Received BNT162b2

	BNT162b2 (30 µg)(N=12,006)	
System Organ Class	n	%
ANY EVENT	190	1.6
CARDIAC DISORDERS	27	0.2
GASTROINTESTINAL DISORDERS	14	0.1
GENERAL DISORDERS & ADMINISTRATION SITE CONDITIONS	7	0.1
HEPATOBILIARY DISORDERS	11	0.1
INFECTIONS AND INFESTATIONS	36	0.3
INJURY, POISONING, PROCEDURAL COMPLICATIONS	16	0.1
MUSCULOSKELETAL & CONNECTIVE TISSUE DISORDERS	9	0.1
NEOPLASMS BENIGN, MALIGNANT, UNSPECIFIED	25	0.2
NERVOUS SYSTEM DISORDERS	23	0.2
RENAL & URINARY DISORDERS	9	0.1
RESPIRATORY, THORACIC & MEDIASTINAL DISORDERS	10	0.1

Adverse Events of Special Interest and other important terms evaluated during the placebo-controlled portion of the clinical trial

FDA Requested AEs of Clinical Interest

- Hypersensitivity/Anaphylaxis
  - Blinded Control period:
    - 3 SAEs of allergic reaction (previously reported) and not related:
      - Anaphylactic reaction after bee sting (BNT162b2 8 days post dose 2)
      - Drug hypersensitivity to antibiotic (BNT162b2 9 days post dose 2)
      - Anaphylactic shock due to ant bite (Placebo 18 days post dose 2)
  - Open Label follow-up period:
    - 1 subject reported anaphylactoid reaction – assessed to be related:
      - Female 17 years old; medical history of multiple allergies; 2 days post dose 3 of BNT162b2 experienced hives; self-administered epinephrine; and resolved 10-30 mins later;
      - Not medically attended
      - Importantly, the participant received a second dose of BNT162b2 outside the study 40 days after the first and no allergic reaction was reported.

FDA Requested AEs of Clinical Interest: Bell's Palsy

- First 6 cases were reported in the initial EUA

Case	Treatment	Period	Sex	Age	Days from last dose	Duration (Days)	Related
1*	BNT162b2	placebo-controlled	Male	53	3	3	Y
2	BNT162b2	placebo-controlled	Male	40	9	68	Y
3**	BNT162b2	placebo-controlled	Male	62	48	30	N
4	BNT162b2	placebo-controlled	Male	70	37	21	N
1	Placebo	placebo-controlled	Female	71	32	15	N
2	Placebo	placebo-controlled	Male	73	102	-	N
5***	BNT162b2	Crossover	Female	19	9	-	Y
6	BNT162b2	Crossover	Female	22	2	-	Y
7	BNT162b2	Crossover	Female	34	4	11	Y
8	BNT162b2	Unblinded followup	Male	51	154	-	N

* Diabetes ** Bell's palsy; TIA *** 3 prior episodes of Bell's palsy

FDA Requested AEs of Clinical Interest (cont.)

- Lymphadenopathy
  - 83 / 21926 (0.4%) in BNT162b2 group
  - 7 / 21921 (0.03%) in placebo group
  - primarily mild to moderate with 3 severe events in BNT162b2 group
    - Median onset between dose 1 and dose 2: 5.5 days for BNT162b2
    - Median onset after dose 2: 2.0 days for BNT162b2
    - Median duration: 5.5 days for BNT162b2

- Appendicitis: None were considered related to study intervention by the investigator
  - Blinded control period
    - BNT162b2 group: 15 / 21926 (0.07%)
    - Placebo group: 12 / 21921 (0.06%)

CDC AESIs

- Only those events where there was an imbalance were investigated in ~46,000 subjects
- Angioedema* 30 (0.14%) vs 29 (0.13%)
- Hypersensitivity*
  - Mostly skin and subcutaneous tissue disorders: BNT162b2 134 (0.61%); Placebo 119 (0.54%)
    - rash BNT162b2 62 (0.28%); Placebo 52 (0.24%)
    - rash maculo-papular BNT162b2 7 (0.03%); Placebo 4 (0.02%)
    - rash papular BNT162b2 1 (0.00%); Placebo 0 (0.0%)

*Standard MedDRA Query

CDC AESIs (cont.)

- Demyelination SMQ
  - Optic neuritis: 2 in the BNT162b2; 0 in placebo
    - 41 year old male, received 2 doses BNT162b2, then quadrivalent influenza vaccine 17 days after dose 2.
      - 80 days after last BNT162b2 dose, developed optic neuritis and visual loss in left eye
      - Investigations were negative; treated with IV methylprednisolone and resolved after 14 days of treatment
      - Not related to vaccine by investigator
    - 30 year old female, received 2 doses of BNT162b2 and had significant medical history of migraines, hypothyroidism and familial hypercholesterolemia
      - 103 days after last BNT162b2 dose, developed severe optic neuritis in right eye with pain, photophobia, and decreased visual acuity and alterations of colour perception
      - MRI showed right optic nerve enhancement; treated with IV methylprednisolone resulted in improvement, but could not be tapered without symptoms recurring
      - Not related by investigator, and ongoing at time of data cutoff.
- Guillain-Barre Syndrome
  - One SAE in the Placebo group

CDC AESIs (cont.): The following terms were not reported in the study

Acute disseminated encephalomyelitis	Narcolepsy
Transverse myelitis	Cataplexy
Multiple sclerosis	Immune thrombocytopaenia
Chronic inflammatory demyelinating polyneuropathy	Thrombotic thrombocytopenic purpura
Encephalitis	Disseminated intravascular coagulation
Myelitis	Kawasaki disease
Encephalomyelitis	Multisystem inflammatory syndrome in children
Meningoencephalitis	Multisystem inflammatory syndrome in adults
Ataxia	Acute respiratory distress syndrome

- 2 cases of bacterial meningitis were reported in the study

Other AESIs of Interest

Additional terms beyond those designated by the CDC as AESIs were evaluated to assess potential imbalances between the BNT162b2 and placebo groups during the blinded placebo-controlled follow-up period.

- **Acute Myocardial Infarction**
  - Acute myocardial infarctions (includes PTs of acute myocardial infarction, acute coronary syndrome, coronary artery occlusion, and myocardial infarction).
    - BNT162b2 (total of **11 events**)
    - Placebo (total of **17 events**)
  - Most of these events had onset distant to (ie, >30 days following) receipt of vaccine or placebo. None of these events were assessed by the investigator as related to study intervention. Outcome was fatal in 2 participants in the placebo group and resolved or resolving in the other cases.

Other AESIs of Interest (cont.)

- **Encephalopathy**
  - 2 events reported in the BNT162b2 group, none in Placebo
    - One was a SAE of toxic encephalopathy 64 days after Dose 2 which resolved 8 days later.
    - One was a SAE of uraemic encephalopathy 36 days after Dose 2 which resolved 3 days later.
    - Both events were assessed by the investigator as not related to study intervention.
- **Multisystem Inflammatory Syndrome**
  - One SAE in the Placebo group of multiple organ dysfunction syndrome secondary to COVID-19.
- **Myocarditis**
  - Once case in the Placebo group

Other AESIs of Interest (cont.)

- **Pericarditis**
  - 1 event reported in the BNT162b2 older age group (66 year old white male)
    - Onset was 29 days after Dose 2 and was ongoing at the time of the data cut-off
    - Not related to study intervention
- **Pulmonary Embolism** (includes PTs of Pulmonary embolism; Pulmonary thrombosis; Pulmonary venous thrombosis; Pulmonary artery thrombosis)
  - **8 cases** in the BNT162b2 group and **8 cases** in Placebo
- **Stroke, Haemorrhagic** (includes PTs of Haemorrhagic stroke; Cerebral haemorrhage; Haemorrhagic cerebral infarction; Basal ganglia haemorrhage; Brain stem haemorrhage; Cerebellar haemorrhage; Subarachnoid haemorrhage; Intraventricular haemorrhage
  - 4 cases in BNT162b2 and 3 cases in placebo group
- **Stroke, Ischaemic**
- 8 cases in BNT162b2 group and 8 cases in Placebo: 8

Other AESIs of Interest (cont.)

- **Thrombocytopenia**: BNT162b2 2 vs Placebo 2
  - Platelet count decrease: 1 in BNT162b2 group; 0 in Placebo group
  - Thrombocytopenia: 1 in BNT162b2 group; 2 in Placebo group

- <u>BNT162b2</u>
  - Late 60s y/o male, med hx alcoholic cirrhosis, esophageal varices & ulcers. On Day 19 following dose 1 participant was hospitalized for 3 days with GI bleed due to esophageal ulcers. Bloodwork revealed a haematocrit 22.9 and **platelet count of 70**. The AE of thrombocytopenia was assessed by investigator as due to cirrhosis (not related to study intervention); ongoing.
  - Mid 80 y/o male, hospitalized with COPD exacerbation, pneumonia (COVID-19 negative) and sepsis on Day 120 post dose 2. Initial labs: haemoglobin 12 g/dL, **platelets 21.4 K/uL**; repeat labs next day: haemoglobin 10.5 g/dL, platelets 177 K/uL The AE of low platelet count was assessed by investigator as not related to study intervention; resolved.

- **Venous Thromboembolism**
  - 9 cases in BNT162b2 and 9 cases in Placebo

None of these venous events were associated with thrombocytopenia.

Pregnancy

Disposition of Participants 16 Years of age and Older, Phase 2/3, Safety Populations who Experienced Pregnancy through 13 March 2021

	BNT162b2[a] (N=22026) n (%)	Placebo[b] (N=22021) n (%)	Total (N=44047) n (%)
Total number of pregnancies	42 (0.2)	47 (0.2)	89 (0.2)
Withdrawal from vaccination due to pregnancy	5 (0.0)	5 (0.0)	10 (0.0)
Timing of pregnancy			
Completed 1 dose	5 (0.0)	8 (0.0)	13 (0.0)
Completed 2 doses	37 (0.2)	39 (0.2)	76 (0.2)
Timing of last dose relative to pregnancy			
Within 30 days of pregnancy	13 (0.1)	21 (0.1)	34 (0.1)
>30 days after pregnancy	29 (0.1)	26 (0.1)	55 (0.1)
Spontaneous Abortions	3 (0.0)	7 (0.0)	10 (0.0)
Miscarriages	3 (0.0)	5 (0.0)	8 (0.0)
Elective Abortions	0	1 (0.0)	1 (0.0)
Fetal demise	0	0	0
Major birth defects	0	0	0

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary

a. Includes data from Dose 1 through 13 March 2021 for participants who originally received BNT162b2.

b. Includes data from Dose 1 to before the first dose of BNT162b2 or through 13 March 2021 for participants who originally received placebo.

Efficacy data

March 13, 2021 Data Cutoff

First COVID-19 Occurrence From 7 Days After Dose 2

Subjects ≥16 Years of Age – Evaluable Efficacy Population – March 13, 2021 Cutoff

Subjects WITHOUT Evidence of Infection Prior to 7 days after Dose 2

	BNT162b2 (30 µg) N=19,993		Placebo N=20,118			
Efficacy Endpoint	**n**	**Surveillance Time (n)**	**n**	**Surveillance Time (n)**	**VE (%)**	**(95% CI)**
First COVID-19 occurrence ≥7 days after Dose 2	**77**	**6.092 (19711)**	**833**	**5.857 (19741)**	**91.1**	**(88.8, 93.1)**

Total surveillance time: 1000 person-years for all subjects within each group at risk for the endpoint.

First COVID-19 Occurrence From 7 Days After Dose 2

Subjects ≥16 Years of Age – Evaluable Efficacy Population

Subjects WITH or WITHOUT Evidence of Infection Prior to 7 days after Dose 2

	BNT162b2 (30 µg) N=21,047		Placebo N=21,210			
Efficacy Endpoint	**n**	**Surveillance Time (n)**	**n**	**Surveillance Time (n)**	**VE (%)**	**(95% CI)**
First COVID-19 occurrence ≥7 days after Dose 2	**81**	**6.340 (20533)**	**854**	**6.110 (20595)**	**90.9**	**(88.5, 92.8)**

Total surveillance time: 1000 person-years for all subjects within each group at risk for the endpoint.

First COVID-19 Occurrence From 7 Days After Dose 2

Subjects ≥16 Years of Age – Evaluable Efficacy Population: Subgroups

Subjects WITH or WITHOUT Evidence of Infection Prior to 7 days after Dose 2

		BNT162b2 N=21,047 n	Placebo N=21,210 n	VE (%)	(95% CI)
Overall			854	90.9	(88.5, 92.8)
Age	16-17 years		11	100.0	(62.4, 100.0)
	18-64 years		715	90.0	(87.3, 92.3)
	65-74 years		102	94.3	(87.1, 98.0)
	≥75 years		26	96.2	(77.2, 99.9)
Sex	Male		399	89.6	(85.8, 92.6)
	Female		455	92.0	(88.8, 94.4)
Race	White		749	91.1	(88.6, 93.2)
	Black or African American		49	92.0	(78.1, 97.9)
	Asian		24	88.0	(60.6, 97.7)
	Multiracial		22	80.1	(46.1, 94.1)
	Not reported		6	100.0	(1.4, 100.0)
Ethnicity	Hispanic/Latino		240	87.1	(81.3, 91.4)
	Non-Hispanic/Non-Latino		614	92.5	(89.9, 94.5)
Country	Argentina		110	85.7	(75.7, 92.1)
	Brazil		82	84.2	(71.9, 91.7)
	Germany		1	100.0	(-3868.6, 100.0)
	South Africa		10	100.0	(56.6, 100.0)
	Turkey		6	100.0	(22.2, 100.0)
	USA		645	92.4	(89.9, 94.4)

First COVID-19 Occurrence From 7 Days After Dose 2

Subjects ≥16 Years of Age – Evaluable Efficacy Population: Risk Factor Subgroups

Subjects WITH or WITHOUT Evidence of Infection Prior to 7 days after Dose 2

		BNT162b2 N=22,166 n	Placebo N=22,320 n		(95% CI)
Overall			854		(88.5, 92.8)
At risk[1]	Yes		402		(87.9, 94.1)
	No		452		(86.9, 93.1)
Age group at risk	16-64 and not at risk		397		(85.4, 92.4)
	16-64 and at risk		329		(87.3, 94.2)
	≥65 and not at risk		55		(89.6, 100.0)
	≥65 and at risk		73		(82.0, 97.2)
Obese[2]	Yes		314		(87.1, 94.3)
	No		540		(87.5, 93.1)
Age group and obese	16-64 and not obese		458		(86.2, 92.5)
	16-64 and obese		268		(86.3, 94.2)
	≥65 and not at obese		82		(87.6, 98.8)
	≥65 and obese	3			(79.5, 98.7)

[1] At least one of Charlson Comorbidity index or obesity
[2] Obesity: BMI ≥ 30 kg/m^2

First COVID-19 Occurrence After Dose 1

	BNT162b2 (30 µg) N=23,040 n	Placebo N=23,037 n		
COVID-19 occurrence after Dose 1		1034		(85.3, 89.9)
After Dose 1 and before Dose 2		110		(40.5, 71.0)
After Dose 1 to <11 days after Dose 1		50		(-26.5, 47.1)
≥11 Days after Dose 1 to before Dose 2		60		(79.5, 97.4)
Dose 2 to 7 days after Dose 2		35		(72.8, 98.3)
≥7 days after Dose 2		889		(88.4, 92.7)
≥7 days after Dose 2 to <2 Months PD2		312		(93.2, 98.0)
≥2 Months after Dose 2 to <4 Months PD2		449		(86.1, 92.6)
≥4 Months after Dose 2	24			(70.8, 88.4)

First Severe COVID-19 Occurrence From 7 Days After Dose 2

Subjects ≥16 Years of Age – Evaluable Efficacy Population

Subjects WITHOUT Evidence of Infection Prior to 7 days after Dose 2

	BNT162b2 (30 µg) N=19,993		Placebo N=20,118			
Efficacy Endpoint	n	Surveillance Time (n)	n	Surveillance Time (n)	VE (%)	(95% CI)
First Severe COVID-19 occurrence ≥7 days after Dose 2	1	6.103 (19711)	21	5.971(19741)	95.3	(71.0, 99.9)

Total surveillance time: 1000 person-years for all subjects within each group at risk for the endpoint.

No apparent SARS-CoV-2 lineage pattern among vaccine breakthrough cases that would suggest meaningfully reduced BNT162b2 efficacy against any variant through 13-March-2021

Summary of SARS-CoV-2 Variants of Concern or Variants of Interest for the First COVID-19 Occurrence

From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects 12 years & older

With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
SARS-CoV-2 Lineage[b] (Location of lineage first identified)	BNT162b2 (30 µg) (N[a]=81) n[c](%)	Placebo (N[a]=873) n[c](%)	Total (N[a]=954) n[c](%)
B.1.1.7 (United Kingdom)	0	3 (0.3)	3 (0.3)
B.1.351 (South Africa)	0	9 (1.0)	9 (0.9)
B.1.427/B.1.429 (USA)	1 (1.2)	23 (2.6)	24 (2.5)
B.1.525 (UK and Nigeria)	0	1 (0.1)	1 (0.1)
B.1.526 (USA)	0	1 (0.1)	1 (0.1)
B.1.616 (France)	0	0	0
B.1.617 (India)	0	0	0
B.1.618 (India)	0	0	0
P.1 (Brazil/Japan)	1 (1.2)	1 (0.1)	2 (0.2)
P.2 (Brazil)	6 (7.4)	40 (4.6)	46 (4.8)
P.3 (Philippines)	0	0	0
Other	66 (81.5)	755 (86.5)	821 (86.1)
Unknown[d]	7 (8.6)	33 (3.8)	40 (4.2)
Not sequenced	0	8 (0.9)	8 (0.8)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of subjects with first COVID-19 occurrence. This value is the denominator for the percentage calculations.
b. Based on PANGO lineages (cov-lineages.org).
c. n = Number of subjects with the specified characteristic.
d. Include indeterminate result and not quantifiable (QNS) samples.

Overall Conclusions

- In Phase 2/3, updated efficacy analysis continued to show that BNT162b2 at 30 µg provided a high level of protection against COVID-19. This was shown in participants across various demographic subgroups. Severe cases were observed predominantly in the placebo group.
- The tolerability and safety profile of BNT162b2 30 µg in participants ≥16 years of age at up to 6 months after Dose 2 was acceptable throughout the follow-up period (to the data cutoff date) and consistent with results previously reported.