Clinical trial results:
A phase 1, Open-Label Dose-Finding Study to Evaluate Safety, Tolerability, and Immunogenicity and Phase 2/3 Placebo-Controlled, Observer-Blinded Safety, Tolerability, and Immunogenicity Study of a SARS-COV-2 RNA Vaccine Candidate Against COVID-19 in Healthy Children

Summary

EudraCT number	2020-005442-42
Trial protocol	FI PL
Global end of trial date	08 December 2023

Results information

Result version number	v1 (current)
This version publication date	21 June 2024
First version publication date	21 June 2024

Trial information

Trial identification

Sponsor protocol code	C4591007

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04816643
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	BioNTech SE
Sponsor organisation address	An der Goldgrube 12, Mainz, Germany, 55131
Public contact	BioNTech clinical trials patient information, BioNTech SE, +49 6131 90840, patients@biontech.de
Scientific contact	BioNTech clinical trials patient information, BioNTech SE, +49 6131 90840, patients@biontech.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-002861-PIP02-20
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 January 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	08 December 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Phase 1: To describe the safety and tolerability profiles of prophylactic BNT162b2 at each dose level in each age group.
Phase 2/3: To define the safety profile of prophylactic BNT162b2 in all participants (selected-dose and obtaining-serum-samples-for potential- troponin I-testing portions of the study) in each age group. To immunobridge the immune response elicited by prophylactic BNT162b2 between Phase 2/3 participants at the dose selected in each age group and participants 16 to 25 years of age from the C4591001 study without serological or virological evidence (up to 1 month after receipt of Dose 2) of past SARS-CoV-2 infection. To immunobridge the immune response elicited by prophylactic BNT162b2 between Phase 2/3 participants at the dose selected in each age group and participants 16 to 25 years of age from the C4591001 study without serological or virological evidence (up to 1 month after receipt of Dose 3) of past SARS-CoV-2 infection.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 March 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 9608
Country: Number of subjects enrolled	Mexico: 353
Country: Number of subjects enrolled	Spain: 413
Country: Number of subjects enrolled	Brazil: 262
Country: Number of subjects enrolled	Finland: 414
Country: Number of subjects enrolled	Poland: 691
Worldwide total number of subjects	11741
EEA total number of subjects	1518

Notes:

Subjects enrolled per age group

In utero	0

Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	2192
Children (2-11 years)	9062
Adolescents (12-17 years)	487
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study consisted of 2 parts, Phase 1 and Phase 2/3. The overall baseline period presented below was created to support display of the demographic characteristics for all study phases. The complete disposition information is presented below in separate tables for each individual phase, respectively.

Pre-assignment

Screening details:

Out of 11837 participants enrolled, 11836 were randomized. However, one participant was enrolled in error and assigned to treatment, of which 11741 were vaccinated.

Period 1

Period 1 title	Baseline Period
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase 1:BNT162b2 (3 mcg):6 Months to < 2 years of age

Arm description:

Participants aged 6 months to less than (<) 2 years of age received 2 doses of 3 microgram (mcg) BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 3 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age

Arm description:

Participants aged 2 to <5 years of age received 2 doses of 3 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 3 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age

Arm description:

Participants aged 2 to <5 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Arm type	Experimental

Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age

Arm description:

Participants aged 5 to <12 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age

Arm description:

Participants aged 5 to <12 years of age received 2 doses of 20 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 2 doses of 20 mcg and 1 dose of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 1: 5 to <12 Years 30/30 mcg

Arm description:

Participants aged 5 to <12 years of age received 2 doses of 30 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 2 doses of 30 mcg and 1 dose of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 1: 5 to <12 Years 30/10 mcg

Arm description:

Participants aged 5 to <12 years of age received 30 mcg in dose 1 and 10 mcg in dose 2 of BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third

dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 30 mcg in dose 1 and 10 mcg in dose 2 of BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age

Arm description:

Participants aged 6 months to <2 years were randomised to receive 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 3 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 2/3: Placebo: 6 months to <2 years of age

Arm description:

Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride solution for injection) administered intramuscularly separated by 21 days interval as part of this study.

Arm title	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age

Arm description:

Participants aged 2 to <5 years were randomised to receive 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 3 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 2/3: Placebo: 2 to <5 years of age

Arm description:

Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride solution for injection) administered intramuscularly separated by 21 days interval as part of this study.

Arm title	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age

Arm description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 2/3: Placebo: 5 to <12 years of age

Arm description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride solution for injection) administered intramuscularly separated by 21 days interval as part of this study.

Arm title	Phase 2/3:Troponin group:BNT162b2(10 mcg):5 to<12 years of age

Arm description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 2/3: Troponin group: Placebo: 5 to <12 years of age

Arm description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride solution for injection) administered intramuscularly separated by 21 days interval as part of this study.

Arm title	Phase 2/3:Troponin group:BNT162b2(30 mcg):12 to<16years of age

Arm description:

Participants aged 12 to <16 years received 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 30 mcg BNT162b2 approximately 175 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 30 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Number of subjects in period 1	Phase 1:BNT162b2 (3 mcg):6 Months to < 2 years of age	Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age
Started	16	16	32
Completed	16	16	32

Number of subjects in period 1	Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age	Phase 1: 5 to <12 Years 30/30 mcg
Started	16	16	4
Completed	16	16	4

Number of subjects in period 1	Phase 1: 5 to <12 Years 30/10 mcg	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Phase 2/3: Placebo: 6 months to <2 years of age
Started	12	1458	718
Completed	12	1458	718

Number of subjects in period 1	Phase 2/3: BNT162b2 (3 mcg):	Phase 2/3: Placebo: 2 to <5 years of age	Phase 2/3: BNT162b2 (10

	2 to <5 years of age		mcg): 5 to <12 years of age
Started	2368	1173	3109
Completed	2368	1173	3109

Number of subjects in period 1	Phase 2/3: Placebo: 5 to <12 years of age	Phase 2/3:Troponin group:BNT162b2(10 mcg):5 to<12 years of age	Phase 2/3: Troponin group: Placebo: 5 to <12 years of age
Started	1538	518	260
Completed	1538	518	260

Number of subjects in period 1	Phase 2/3:Troponin group:BNT162b2(30 mcg):12 to<16years of age
Started	487
Completed	487

Period 2

Period 2 title	Phase 1
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age

Arm description:

Participants aged 6 months to less than (<) 2 years of age received 2 doses of 3 microgram (mcg) BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 3 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age

Arm description:

Participants aged 2 to <5 years of age received 2 doses of 3 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Arm type	Experimental

Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 3 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age

Arm description:

Participants aged 2 to <5 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age

Arm description:

Participants aged 5 to <12 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age

Arm description:

Participants aged 5 to <12 years of age received 2 doses of 20 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 2 doses of 20 mcg and 1 dose of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age

Arm description:

Participants aged 5 to <12 years of age received 2 doses of 30 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2

approximately 175 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 2 doses of 30 mcg and 1 dose of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age

Arm description:

Participants aged 5 to <12 years of age received 30 mcg in dose 1 and 10 mcg in dose 2 of BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 30 mcg in dose 1 and 10 mcg in dose 2 of BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Number of subjects in period 2[1]	Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age	Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age
Started	16	16	32
Completed	8	7	14
Not completed	8	9	18
Withdrawal by parent/guardian/subject	1	3	4
Unspecified	6	3	4
Lost to follow-up	-	1	2
Protocol deviation	1	2	8

Number of subjects in period 2[1]	Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age	Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age
Started	16	16	4
Completed	2	3	2
Not completed	14	13	2
Withdrawal by parent/guardian/subject	1	2	-
Unspecified	8	2	1
Lost to follow-up	-	-	-
Protocol deviation	5	9	1

Number of subjects in period 2[1]	Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age
Started	12
Completed	1
Not completed	11
Withdrawal by parent/guardian/subject	1
Unspecified	4
Lost to follow-up	-
Protocol deviation	6

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: The participants enrolled in both periods are different.

Period 3

Period 3 title	Phase 2/3
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	No
Arm title	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age

Arm description:

Participants aged 6 months to <2 years were randomized to received 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 3 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 2/3: Placebo: 6 months to <2 years

Arm description:

Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride solution for injection) administered intramuscularly.

Arm title	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age

Arm description:

Participants aged 2 to <5 years were randomised to receive 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 3 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 2/3: Placebo: 2 to <5 years of age

Arm description:

Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride solution for injection) administered intramuscularly separated by 21 days interval as part of this study.

Arm title	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age

Arm description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 2/3: Placebo: 5 to <12 years of age

Arm description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride solution for injection) administered

intramuscularly separated by 21 days interval as part of this study.

Arm title	Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years

Arm description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Arm title	Phase 2/3:Troponin group:Placebo:5 to <12 years

Arm description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride solution for injection) administered intramuscularly separated by 21 days interval as part of this study.

Arm title	Phase 2/3:Troponin group:BNT162b2 (30 mcg):12 to <16 years

Arm description:

Participants aged 12 to <16 years were received 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 30 mcg BNT162b2 approximately 175 days after vaccination 2.

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received 3 doses of 30 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

Number of subjects in period 3	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Phase 2/3: Placebo: 6 months to <2 years	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age
Started	1458	718	2368
Completed	712	261	1215
Not completed	746	457	1153
Withdrawal by parent/guardian/subject	199	196	427
Physician decision	3	1	2
Refused further study procedures	-	-	-
Pregnancy	-	-	-
Adverse event	1	-	3
Unspecified	465	221	464
Lost to follow-up	53	23	109
Protocol deviation	25	16	148

Number of subjects in period 3	Phase 2/3: Placebo: 2 to <5 years of age	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 2/3: Placebo: 5 to <12 years of age
Started	1173	3109	1538
Completed	406	1604	636
Not completed	767	1505	902
Withdrawal by parent/guardian/subject	458	816	543
Physician decision	1	-	-
Refused further study procedures	-	2	-
Pregnancy	-	-	-
Adverse event	-	-	-
Unspecified	171	86	47
Lost to follow-up	55	126	41
Protocol deviation	82	475	271

Number of subjects in period 3	Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years	Phase 2/3:Troponin group:Placebo:5 to <12 years	Phase 2/3:Troponin group:BNT162b2 (30 mcg):12 to <16 years
Started	518	260	487
Completed	395	188	424
Not completed	123	72	63
Withdrawal by parent/guardian/subject	66	37	40
Physician decision	1	1	-
Refused further study procedures	-	-	-
Pregnancy	-	-	2
Adverse event	-	-	-
Unspecified	11	4	-

Lost to follow-up	14	10	15
Protocol deviation	31	20	6

Baseline characteristics

Reporting groups

Reporting group title	Phase 1:BNT162b2 (3 mcg):6 Months to < 2 years of age

Reporting group description:

Participants aged 6 months to less than (<) 2 years of age received 2 doses of 3 microgram (mcg) BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Reporting group title	Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age

Reporting group description:

Participants aged 2 to <5 years of age received 2 doses of 3 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Reporting group title	Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age

Reporting group description:

Participants aged 2 to <5 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Reporting group title	Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age

Reporting group description:

Participants aged 5 to <12 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Reporting group title	Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age

Reporting group description:

Participants aged 5 to <12 years of age received 2 doses of 20 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Reporting group title	Phase 1: 5 to <12 Years 30/30 mcg

Reporting group description:

Participants aged 5 to <12 years of age received 2 doses of 30 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Reporting group title	Phase 1: 5 to <12 Years 30/10 mcg

Reporting group description:

Participants aged 5 to <12 years of age received 30 mcg in dose 1 and 10 mcg in dose 2 of BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Reporting group title	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age

Reporting group description:

Participants aged 6 months to <2 years were randomised to receive 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Reporting group title	Phase 2/3: Placebo: 6 months to <2 years of age

Reporting group description:

Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

Reporting group title	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age

Reporting group description:

Participants aged 2 to <5 years were randomised to receive 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Reporting group title	Phase 2/3: Placebo: 2 to <5 years of age

Reporting group description:

Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

Reporting group title	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Reporting group title	Phase 2/3: Placebo: 5 to <12 years of age

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

Reporting group title	Phase 2/3:Troponin group:BNT162b2(10 mcg):5 to<12 years of age

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Reporting group title	Phase 2/3: Troponin group: Placebo: 5 to <12 years of age

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

Reporting group title	Phase 2/3:Troponin group:BNT162b2(30 mcg):12 to<16years of age

Reporting group description:

Participants aged 12 to <16 years received 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 30 mcg BNT162b2 approximately 175 days after vaccination 2.

Reporting group values	Phase 1:BNT162b2 (3 mcg):6 Months to < 2 years of age	Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age
Number of subjects	16	16	32
Age Categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	16	0	0
Children (2-11 years)	0	16	32
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender Categorical Units: Participants			
Female	6	7	13
Male	10	9	19
Race Units: Subjects			
White	13	12	25
Black or African American	0	0	2
Asian	1	1	2
Multiracial	2	3	2
American Indian or Alaska Native	0	0	1
Native Hawaiian or other Pacific Islander	0	0	0

Not reported	0	0	0
Ethnicity Units: Subjects			
Hispanic/Latino	3	0	1
Non-Hispanic/non-Latino	13	16	31
Not reported	0	0	0

Reporting group values	Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age	Phase 1: 5 to <12 Years 30/30 mcg
Number of subjects	16	16	4
Age Categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	16	16	4
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender Categorical Units: Participants			
Female	11	6	1
Male	5	10	3
Race Units: Subjects			
White	11	13	4
Black or African American	3	0	0
Asian	2	2	0
Multiracial	0	1	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
Not reported	0	0	0
Ethnicity Units: Subjects			
Hispanic/Latino	2	0	2
Non-Hispanic/non-Latino	14	16	2
Not reported	0	0	0

Reporting group values	Phase 1: 5 to <12 Years 30/10 mcg	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Phase 2/3: Placebo: 6 months to <2 years of age
Number of subjects	12	1458	718
Age Categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0

Infants and toddlers (28 days-23 months)	0	1458	718
Children (2-11 years)	12	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender Categorical Units: Participants			
Female	6	728	372
Male	6	730	346
Race Units: Subjects			
White	10	1126	562
Black or African American	0	73	34
Asian	1	101	51
Multiracial	1	149	65
American Indian or Alaska Native	0	4	1
Native Hawaiian or other Pacific Islander	0	0	0
Not reported	0	5	5
Ethnicity Units: Subjects			
Hispanic/Latino	0	248	93
Non-Hispanic/non-Latino	12	1205	620
Not reported	0	5	5

Reporting group values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 2/3: Placebo: 2 to <5 years of age	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age
Number of subjects	2368	1173	3109
Age Categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	2368	1173	3109
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender Categorical Units: Participants			
Female	1197	570	1500
Male	1171	603	1609
Race Units: Subjects			
White	1870	913	2404
Black or African American	138	71	179
Asian	147	92	256

Multiracial	189	86	235
American Indian or Alaska Native	4	4	13
Native Hawaiian or other Pacific Islander	2	1	10
Not reported	18	6	12
Ethnicity Units: Subjects			
Hispanic/Latino	426	193	526
Non-Hispanic/non-Latino	1934	979	2579
Not reported	8	1	4

Reporting group values	Phase 2/3: Placebo: 5 to <12 years of age	Phase 2/3:Troponin group:BNT162b2(10 mcg):5 to<12 years of age	Phase 2/3: Troponin group: Placebo: 5 to <12 years of age
Number of subjects	1538	518	260
Age Categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	1538	518	260
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender Categorical Units: Participants			
Female	759	252	120
Male	779	266	140
Race Units: Subjects			
White	1199	425	219
Black or African American	101	19	11
Asian	118	49	16
Multiracial	106	23	13
American Indian or Alaska Native	4	1	1
Native Hawaiian or other Pacific Islander	0	0	0
Not reported	10	1	0
Ethnicity Units: Subjects			
Hispanic/Latino	265	52	34
Non-Hispanic/non-Latino	1273	466	226
Not reported	0	0	0

Reporting group values	Phase 2/3:Troponin group:BNT162b2(30 mcg):12 to<16years of age	Total	
Number of subjects	487	11741	

Age Categorical Units: Participants			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	2192	
Children (2-11 years)	0	9062	
Adolescents (12-17 years)	487	487	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Gender Categorical Units: Participants			
Female	216	5764	
Male	271	5977	
Race Units: Subjects			
White	228	9034	
Black or African American	40	671	
Asian	4	843	
Multiracial	1	876	
American Indian or Alaska Native	209	242	
Native Hawaiian or other Pacific Islander	0	13	
Not reported	5	62	
Ethnicity Units: Subjects			
Hispanic/Latino	422	2267	
Non-Hispanic/non-Latino	65	9451	
Not reported	0	23	

End points

End points reporting groups

Reporting group title	Phase 1:BNT162b2 (3 mcg):6 Months to < 2 years of age
Reporting group description:	
Participants aged 6 months to less than (<) 2 years of age received 2 doses of 3 microgram (mcg) BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.	
Reporting group title	Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age
Reporting group description:	
Participants aged 2 to <5 years of age received 2 doses of 3 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.	
Reporting group title	Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age
Reporting group description:	
Participants aged 2 to <5 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.	
Reporting group title	Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age
Reporting group description:	
Participants aged 5 to <12 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.	
Reporting group title	Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age
Reporting group description:	
Participants aged 5 to <12 years of age received 2 doses of 20 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.	
Reporting group title	Phase 1: 5 to <12 Years 30/30 mcg
Reporting group description:	
Participants aged 5 to <12 years of age received 2 doses of 30 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.	
Reporting group title	Phase 1: 5 to <12 Years 30/10 mcg
Reporting group description:	
Participants aged 5 to <12 years of age received 30 mcg in dose 1 and 10 mcg in dose 2 of BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.	
Reporting group title	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age
Reporting group description:	
Participants aged 6 months to <2 years were randomised to receive 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.	
Reporting group title	Phase 2/3: Placebo: 6 months to <2 years of age
Reporting group description:	
Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.	
Reporting group title	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age
Reporting group description:	
Participants aged 2 to <5 years were randomised to receive 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.	
Reporting group title	Phase 2/3: Placebo: 2 to <5 years of age
Reporting group description:	
Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.	

Reporting group title	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Reporting group title	Phase 2/3: Placebo: 5 to <12 years of age

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

Reporting group title	Phase 2/3:Troponin group:BNT162b2(10 mcg):5 to<12 years of age

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Reporting group title	Phase 2/3: Troponin group: Placebo: 5 to <12 years of age

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

Reporting group title	Phase 2/3:Troponin group:BNT162b2(30 mcg):12 to<16years of age

Reporting group description:

Participants aged 12 to <16 years received 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 30 mcg BNT162b2 approximately 175 days after vaccination 2.

Reporting group title	Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age

Reporting group description:

Participants aged 6 months to less than (<) 2 years of age received 2 doses of 3 microgram (mcg) BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Reporting group title	Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age

Reporting group description:

Participants aged 2 to <5 years of age received 2 doses of 3 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Reporting group title	Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age

Reporting group description:

Participants aged 2 to <5 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Reporting group title	Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age

Reporting group description:

Participants aged 5 to <12 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Reporting group title	Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age

Reporting group description:

Participants aged 5 to <12 years of age received 2 doses of 20 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Reporting group title	Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age

Reporting group description:

Participants aged 5 to <12 years of age received 2 doses of 30 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Reporting group title	Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age

Reporting group description:

Participants aged 5 to <12 years of age received 30 mcg in dose 1 and 10 mcg in dose 2 of BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third

dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Reporting group title	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age

Reporting group description:

Participants aged 6 months to <2 years were randomized to received 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Reporting group title	Phase 2/3: Placebo: 6 months to <2 years

Reporting group description:

Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly.

Reporting group title	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age

Reporting group description:

Participants aged 2 to <5 years were randomised to receive 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

Reporting group title	Phase 2/3: Placebo: 2 to <5 years of age

Reporting group description:

Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

Reporting group title	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Reporting group title	Phase 2/3: Placebo: 5 to <12 years of age

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

Reporting group title	Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

Reporting group title	Phase 2/3:Troponin group:Placebo:5 to <12 years

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

Reporting group title	Phase 2/3:Troponin group:BNT162b2 (30 mcg):12 to <16 years

Reporting group description:

Participants aged 12 to <16 years were received 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 30 mcg BNT162b2 approximately 175 days after vaccination 2.

Subject analysis set title	Phase 1: 5 to <12 Years BNT162b2 10 mcg
Subject analysis set type	Per protocol

Subject analysis set description:

Participants aged 5 to <12 years who received the third dose of 10 mcg BNT162b2 as part of this study were included.

Subject analysis set title	Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years
Subject analysis set type	Per protocol

Subject analysis set description:

Participants aged 16 to 25 years from study C4591001 (NCT04816643) who received 2 doses of original BNT162b2 30 mcg were included.

Subject analysis set title	Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 3 mcg)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants aged 2 to <5 years at the time of receiving third dose received 3 mcg BNT162b2intramuscularly as part of this study.

Subject analysis set title	Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 10 mcg)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants in the 2 to < 5years of age group who aged up to 5 years at the time of the 3rd dose received the age-appropriate dose of 10 mcg BNT162b2 intramuscularly.

Subject analysis set title	Phase 2/3: BNT162b2 (10 mcg) 3-Dose Set
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants aged 5 to <12 years who received Dose 3 and completed 1 month post-Dose 3 visit in the Dose 3 evaluable immunogenicity population without evidence of prior infection up 1 month post-Dose 3 were included.

Subject analysis set title	Phase 2/3: BNT162b2 30 mcg 16-25 Years
Subject analysis set type	Per protocol

Subject analysis set description:

Participants aged >=12 to <16 years who received 3 doses of original BNT162b2 30 mcg were included.

Subject analysis set title	Phase 2/3: C4591001: Placebo 16-25 Years
Subject analysis set type	Per protocol

Subject analysis set description:

Participants aged >=12 to <16 years who received placebo in Phase 2/3 were included.

Subject analysis set title	Ph2/3:BNT162b2 3mcg:6M-<5Y:WoEI:evaluable efficacy(3dose)set
Subject analysis set type	Full analysis

Subject analysis set description:

Phase 2/3 (Ph2/3):Participants aged >=6 months to <5 years (6M-<5Y) in evaluable efficacy (3-Dose) population who received 3 doses of original BNT162b2 3 mcg during the blinded follow up period without evidence of infection(WoEI) prior to 7 days after Dose 3.

Subject analysis set title	Phase2/3:Placebo:6M-<5Y):WoEI:evaluable efficacy(3-dose)set
Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged >=6 months to <5 years in evaluable efficacy (3-Dose) population who received 3 doses of placebo during the blinded follow up period without evidence of infection prior to 7 days after Dose 3.

Subject analysis set title	Phase 2/3:BNT162b2 3 mcg 6M<5Y:evaluable efficacy(3-dose)set
Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged >=6 months to <5 years in evaluable efficacy (3-Dose) population who received 3 doses of original BNT162b2 3 mcg during the blinded follow up period with and without evidence of infection prior to 7 days after Dose 3.

Subject analysis set title	Phase 2/3:Placebo 6M-<5Y:evaluable efficacy(3-dose)set
Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged >=6 months to <5 years in evaluable efficacy (3-Dose) population who received 3 doses of placebo during the blinded follow up period with and without evidence of infection prior to 7 days after Dose 3.

Subject analysis set title	Ph2/3:BNT162b2 3 mcg 5-<12Y:WoEI:evaluable efficacy(3-dose)set
Subject analysis set type	Full analysis

Subject analysis set description:

Phase 2/3(Ph2/3):Participants aged 5 to <12 years in evaluable efficacy (3-Dose) population who received 3 doses of original BNT162b2 3 mcg during the blinded follow up period without evidence of infection (WoEI)prior to 7 days after Dose 3.

Subject analysis set title	Phase 2/3:Placebo 5 to <12Y:WoEI:evaluable efficacy(3-dose)set

Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged 5 to <12 years in evaluable efficacy (3-Dose) population who received 3 doses of placebo during the blinded follow up period without evidence of infection prior to 7 days after Dose 3.

Subject analysis set title	Phase 2/3:BNT162b2 3 mcg 5-<12Y:evaluable efficacy(3-dose)set
Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged 5 to <12 years in evaluable efficacy (3-Dose) population who received 3 doses of original BNT162b2 3 mcg during the blinded follow up period with and without evidence of infection prior to 7 days after Dose 3.

Subject analysis set title	Phase 2/3:Placebo 5-<12Y:evaluable efficacy(3-dose)set
Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged 5 to <12 years in evaluable efficacy (3-Dose) population who received 3 doses of placebo during the blinded follow up period with and without evidence of infection prior to 7 days after Dose 3.

Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=5 to <12 Years of age

End point title	Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=5 to <12 Years of age[1]

End point description:

Local reactions were collected in electronic diary (e-diary) or during unscheduled clinical assessments from Day 1 to 7 after Dose 1. Redness and swelling were measured and recorded in measuring device unit (mdu) where, 1 mdu =0.5 centimeter(cm) & were graded as mild(>=0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe(>7.0 cm)& Grade 4 (G4) (necrosis[redness and swelling]or exfoliative dermatitis[redness]).Pain at injection site was graded as mild(did not interfere with activity),moderate (interfered with activity),severe (prevented daily activity) & G4 Emergency room (ER) visit or hospitalisation).G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% Confidence interval was based on Clopper and Pearson method. Safety population consisted of all participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age	Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age	Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	4	12
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	12.5 (1.6 to 38.3)	0 (0.0 to 20.6)	100.0 (39.8 to 100.0)	16.7 (2.1 to 48.4)
Redness: Mild	6.3 (0.2 to 30.2)	0 (0.0 to 20.6)	25.0 (0.6 to 80.6)	0 (0.0 to 26.5)
Redness: Moderate	6.3 (0.2 to 30.2)	0 (0.0 to 20.6)	75.0 (19.4 to 99.4)	16.7 (2.1 to 48.4)
Redness: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Redness: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)

Swelling: Any	18.8 (4.0 to 45.6)	6.3 (0.2 to 30.2)	50.0 (6.8 to 93.2)	8.3 (0.2 to 38.5)
Swelling: Mild	6.3 (0.2 to 30.2)	0 (0.0 to 20.6)	25.0 (0.6 to 80.6)	0 (0.0 to 26.5)
Swelling: Moderate	12.5 (1.6 to 38.3)	6.3 (0.2 to 30.2)	25.0 (0.6 to 80.6)	8.3 (0.2 to 38.5)
Swelling: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Swelling: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Pain at the injection site: Any	87.5 (61.7 to 98.4)	93.8 (69.8 to 99.8)	100.0 (39.8 to 100.0)	83.3 (51.6 to 97.9)
Pain at the injection site: Mild	68.8 (41.3 to 89.0)	56.3 (29.9 to 80.2)	50.0 (6.8 to 93.2)	50.0 (21.1 to 78.9)
Pain at the injection site: Moderate	18.8 (4.0 to 45.6)	37.5 (15.2 to 64.6)	50.0 (6.8 to 93.2)	33.3 (9.9 to 65.1)
Pain at the injection site: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Pain at the injection site: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=5 to <12 Years of age

End point title	Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=5 to <12 Years of age[2]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation. G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age	Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age	Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	4	12
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	37.5 (15.2 to 64.6)	18.8 (4.0 to 45.6)	75.0 (19.4 to 99.4)	16.7 (2.1 to 48.4)
Redness: Mild	25.0 (7.3 to 52.4)	6.3 (0.2 to 30.2)	25.0 (0.6 to 80.6)	8.3 (0.2 to 38.5)

Redness: Moderate	12.5 (1.6 to 38.3)	12.5 (1.6 to 38.3)	25.0 (0.6 to 80.6)	8.3 (0.2 to 38.5)
Redness: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	25.0 (0.6 to 80.6)	0 (0.0 to 26.5)
Redness: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Swelling: Any	31.3 (11.0 to 58.7)	18.8 (4.0 to 45.6)	50.0 (6.8 to 93.2)	0 (0.0 to 26.5)
Swelling: Mild	12.5 (1.6 to 38.3)	0 (0.0 to 20.6)	50.0 (6.8 to 93.2)	0 (0.0 to 26.5)
Swelling: Moderate	18.8 (4.0 to 45.6)	18.8 (4.0 to 45.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Swelling: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Swelling: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Pain at the injection site: Any	87.5 (61.7 to 98.4)	75.0 (47.6 to 92.7)	100.0 (39.8 to 100.0)	91.7 (61.5 to 99.8)
Pain at the injection site: Mild	75.0 (47.6 to 92.7)	50.0 (24.7 to 75.3)	50.0 (6.8 to 93.2)	83.3 (51.6 to 97.9)
Pain at the injection site: Moderate	12.5 (1.6 to 38.3)	25.0 (7.3 to 52.4)	50.0 (6.8 to 93.2)	8.3 (0.2 to 38.5)
Pain at the injection site: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Pain at the injection site: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=5 to <12 Years of age

End point title	Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=5 to <12 Years of age[3]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and G4 ER visit or hospitalisation. Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention. All participants aged 5 to <12 years were administered BNT 10 mcg at Dose 3; hence, only BNT 10 mcg arm is reported.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: 5 to <12 Years BNT162b2 10 mcg			
Subject group type	Subject analysis set			
Number of subjects analysed	38			
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	28.9 (15.4 to 45.9)			
Redness: Mild	21.1 (9.6 to 37.3)			
Redness: Moderate	7.9 (1.7 to 21.4)			
Redness: Severe	0 (0.0 to 9.3)			
Redness: Grade 4	0 (0.0 to 9.3)			
Swelling: Any	13.2 (4.4 to 28.1)			
Swelling: Mild	10.5 (2.9 to 24.8)			
Swelling: Moderate	2.6 (0.1 to 13.8)			
Swelling: Severe	0 (0.0 to 9.3)			
Swelling: Grade 4	0 (0.0 to 9.3)			
Pain at the injection site: Any	86.8 (71.9 to 95.6)			
Pain at the injection site: Mild	68.4 (51.3 to 82.5)			
Pain at the injection site: Moderate	18.4 (7.7 to 34.3)			
Pain at the injection site: Severe	0 (0.0 to 9.3)			
Pain at the injection site: Grade 4	0 (0.0 to 9.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=5 to <12 Years of age

End point title	Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=5 to <12 Years of age[4]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Fever:oral temperature >= 38.0 degree Celsius (deg C);categorised as Fever:oral temperature >=38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C,>38.9 to 40.0 deg C& >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate(some interference with activity),severe(prevented daily routine activity).Vomiting:mild:1-2 times in 24 hours(h),moderate:>2 times in 24h,severe:required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24h,moderate:4-5 loose stools in 24h,severe:6 or more loose stools in 24h.G4 for all events:ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in CRF within 7 days after vaccination were also included.Exact 95%CI based on Clopper and Pearson method. Safety population

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age	Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age	Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	4	12
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 deg C	6.3 (0.2 to 30.2)	6.3 (0.2 to 30.2)	0 (0.0 to 60.2)	33.3 (9.9 to 65.1)
Fever:38.0 to 38.4 deg C	6.3 (0.2 to 30.2)	6.3 (0.2 to 30.2)	0 (0.0 to 60.2)	16.7 (2.1 to 48.4)
Fever: >38.4 to 38.9 deg C	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	16.7 (2.1 to 48.4)
Fever: >38.9 to 40.0 deg C	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Fever: >40.0 deg C	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Fatigue: Any	50.0 (24.7 to 75.3)	68.8 (41.3 to 89.0)	100.0 (39.8 to 100.0)	50.0 (21.1 to 78.9)
Fatigue: Mild	37.5 (15.2 to 64.6)	31.3 (11.0 to 58.7)	25.0 (0.6 to 80.6)	16.7 (2.1 to 48.4)
Fatigue: Moderate	12.5 (1.6 to 38.3)	37.5 (15.2 to 64.6)	75.0 (19.4 to 99.4)	33.3 (9.9 to 65.1)
Fatigue: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Fatigue: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Headache: Any	25.0 (7.3 to 52.4)	31.3 (11.0 to 58.7)	75.0 (19.4 to 99.4)	33.3 (9.9 to 65.1)
Headache: Mild	18.8 (4.0 to 45.6)	31.3 (11.0 to 58.7)	50.0 (6.8 to 93.2)	25.0 (5.5 to 57.2)
Headache: Moderate	6.3 (0.2 to 30.2)	0 (0.0 to 20.6)	25.0 (0.6 to 80.6)	8.3 (0.2 to 38.5)
Headache: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Headache: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Chills: Any	0 (0.0 to 20.6)	25.0 (7.3 to 52.4)	50.0 (6.8 to 93.2)	16.7 (2.1 to 48.4)
Chills: Mild	0 (0.0 to 20.6)	18.8 (4.0 to 45.6)	0 (0.0 to 60.2)	8.3 (0.2 to 38.5)
Chills: Moderate	0 (0.0 to 20.6)	6.3 (0.2 to 30.2)	50.0 (6.8 to 93.2)	8.3 (0.2 to 38.5)
Chills: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Chills: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Vomiting: Any	0 (0.0 to 20.6)	6.3 (0.2 to 30.2)	0 (0.0 to 60.2)	8.3 (0.2 to 38.5)
Vomiting: Mild	0 (0.0 to 20.6)	6.3 (0.2 to 30.2)	0 (0.0 to 60.2)	8.3 (0.2 to 38.5)
Vomiting: Moderate	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Vomiting: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Vomiting: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Diarrhea: Any	6.3 (0.2 to 30.2)	6.3 (0.2 to 30.2)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Diarrhea: Mild	6.3 (0.2 to 30.2)	6.3 (0.2 to 30.2)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Diarrhea: Moderate	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Diarrhea: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)

Diarrhea: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
New or worsened muscle pain: Any	12.5 (1.6 to 38.3)	25.0 (7.3 to 52.4)	100.0 (39.8 to 100.0)	0 (0.0 to 26.5)
New or worsened muscle pain: Mild	6.3 (0.2 to 30.2)	25.0 (7.3 to 52.4)	25.0 (0.6 to 80.6)	0 (0.0 to 26.5)
New or worsened muscle pain: Moderate	6.3 (0.2 to 30.2)	0 (0.0 to 20.6)	75.0 (19.4 to 99.4)	0 (0.0 to 26.5)
New or worsened muscle pain: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
New or worsened muscle pain: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
New or worsened joint pain: Any	6.3 (0.2 to 30.2)	6.3 (0.2 to 30.2)	25.0 (0.6 to 80.6)	8.3 (0.2 to 38.5)
New or worsened joint pain: Mild	6.3 (0.2 to 30.2)	6.3 (0.2 to 30.2)	0 (0.0 to 60.2)	8.3 (0.2 to 38.5)
New or worsened joint pain: Moderate	0 (0.0 to 20.6)	0 (0.0 to 20.6)	25.0 (0.6 to 80.6)	0 (0.0 to 26.5)
New or worsened joint pain: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
New or worsened joint pain: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=5 to <12 Years of age

End point title	Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=5 to <12 Years of age[5]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C.Fatigue, headache,chills, new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age	Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age	Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	4	12
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 deg C	12.5 (1.6 to 38.3)	18.8 (4.0 to 45.6)	100.0 (39.8 to 100.0)	0 (0.0 to 26.5)

Fever: 38.0 to 38.4 deg C	0 (0.0 to 20.6)	6.3 (0.2 to 30.2)	75.0 (19.4 to 99.4)	0 (0.0 to 26.5)
Fever: >38.4 to 38.9 deg C	6.3 (0.2 to 30.2)	6.3 (0.2 to 30.2)	25.0 (0.6 to 80.6)	0 (0.0 to 26.5)
Fever: >38.9 to 40.0 deg C	6.3 (0.2 to 30.2)	6.3 (0.2 to 30.2)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Fever: >40.0 deg C	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Fatigue: Any	68.8 (41.3 to 89.0)	62.5 (35.4 to 84.8)	100.0 (39.8 to 100.0)	75.0 (42.8 to 94.5)
Fatigue: Mild	43.8 (19.8 to 70.1)	25.0 (7.3 to 52.4)	25.0 (0.6 to 80.6)	58.3 (27.7 to 84.8)
Fatigue: Moderate	25.0 (7.3 to 52.4)	37.5 (15.2 to 64.6)	75.0 (19.4 to 99.4)	16.7 (2.1 to 48.4)
Fatigue: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Fatigue: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Headache: Any	50.0 (24.7 to 75.3)	56.3 (29.9 to 80.2)	75.0 (19.4 to 99.4)	33.3 (9.9 to 65.1)
Headache: Mild	25.0 (7.3 to 52.4)	25.0 (7.3 to 52.4)	25.0 (0.6 to 80.6)	25.0 (5.5 to 57.2)
Headache: Moderate	25.0 (7.3 to 52.4)	31.3 (11.0 to 58.7)	50.0 (6.8 to 93.2)	8.3 (0.2 to 38.5)
Headache: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Headache: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Chills: Any	31.3 (11.0 to 58.7)	43.8 (19.8 to 70.1)	75.0 (19.4 to 99.4)	33.3 (9.9 to 65.1)
Chills: Mild	25.0 (7.3 to 52.4)	25.0 (7.3 to 52.4)	75.0 (19.4 to 99.4)	33.3 (9.9 to 65.1)
Chills: Moderate	6.3 (0.2 to 30.2)	18.8 (4.0 to 45.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Chills: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Chills: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Vomiting: Any	0 (0.0 to 20.6)	0 (0.0 to 20.6)	25.0 (0.6 to 80.6)	8.3 (0.2 to 38.5)
Vomiting: Mild	0 (0.0 to 20.6)	0 (0.0 to 20.6)	25.0 (0.6 to 80.6)	8.3 (0.2 to 38.5)
Vomiting: Moderate	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Vomiting: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Vomiting: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Diarrhea: Any	6.3 (0.2 to 30.2)	0 (0.0 to 20.6)	50.0 (6.8 to 93.2)	0 (0.0 to 26.5)
Diarrhea: Mild	6.3 (0.2 to 30.2)	0 (0.0 to 20.6)	50.0 (6.8 to 93.2)	0 (0.0 to 26.5)
Diarrhea: Moderate	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Diarrhea: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
Diarrhea: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
New or worsened muscle pain: Any	0 (0.0 to 20.6)	18.8 (4.0 to 45.6)	50.0 (6.8 to 93.2)	8.3 (0.2 to 38.5)
New or worsened muscle pain: Mild	0 (0.0 to 20.6)	18.8 (4.0 to 45.6)	0 (0.0 to 60.2)	8.3 (0.2 to 38.5)
New or worsened muscle pain: Moderate	0 (0.0 to 20.6)	0 (0.0 to 20.6)	50.0 (6.8 to 93.2)	0 (0.0 to 26.5)
New or worsened muscle pain: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
New or worsened muscle pain: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
New or worsened joint pain: Any	0 (0.0 to 20.6)	0 (0.0 to 20.6)	25.0 (0.6 to 80.6)	0 (0.0 to 26.5)
New or worsened joint pain: Mild	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)
New or worsened joint pain: Moderate	0 (0.0 to 20.6)	0 (0.0 to 20.6)	25.0 (0.6 to 80.6)	0 (0.0 to 26.5)
New or worsened joint pain: Severe	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)

New or worsened joint pain: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 20.6)	0 (0.0 to 60.2)	0 (0.0 to 26.5)

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 3:>=5 to <12 Years of age

End point title	Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 3:>=5 to <12 Years of age[6]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population was used.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: 5 to <12 Years BNT162b2 10 mcg			
Subject group type	Subject analysis set			
Number of subjects analysed	38			
Units: Percentage of participants				
number (confidence interval 95%)				
Fever:>=38.0 deg C	2.6 (0.1 to 13.8)			
Fever:38.0 to 38.4 deg C	0 (0.0 to 9.3)			
Fever: >38.4 to 38.9 deg C	0 (0.0 to 9.3)			
Fever: >38.9 to 40.0 deg C	2.6 (0.1 to 13.8)			
Fever: >40.0 deg C	0 (0.0 to 9.3)			
Fatigue: Any	39.5 (24.0 to 56.6)			
Fatigue: Mild	21.1 (9.6 to 37.3)			
Fatigue: Moderate	15.8 (6.0 to 31.3)			
Fatigue: Severe	2.6 (0.1 to 13.8)			
Fatigue: Grade 4	0 (0.0 to 9.3)			

Headache: Any	34.2 (19.6 to 51.4)			
Headache: Mild	21.1 (9.6 to 37.3)			
Headache: Moderate	10.5 (2.9 to 24.8)			
Headache: Severe	2.6 (0.1 to 13.8)			
Headache: Grade 4	0 (0.0 to 9.3)			
Chills: Any	15.8 (6.0 to 31.3)			
Chills: Mild	13.2 (4.4 to 28.1)			
Chills: Moderate	2.6 (0.1 to 13.8)			
Chills: Severe	0 (0.0 to 9.3)			
Chills: Grade 4	0 (0.0 to 9.3)			
Vomiting: Any	2.6 (0.1 to 13.8)			
Vomiting: Mild	2.6 (0.1 to 13.8)			
Vomiting: Moderate	0 (0.0 to 9.3)			
Vomiting: Severe	0 (0.0 to 9.3)			
Vomiting: Grade 4	0 (0.0 to 9.3)			
Diarrhea: Any	0 (0.0 to 9.3)			
Diarrhea: Mild	0 (0.0 to 9.3)			
Diarrhea: Moderate	0 (0.0 to 9.3)			
Diarrhea: Severe	0 (0.0 to 9.3)			
Diarrhea: Grade 4	0 (0.0 to 9.3)			
New or worsened muscle pain: Any	7.9 (1.7 to 21.4)			
New or worsened muscle pain: Mild	2.6 (0.1 to 13.8)			
New or worsened muscle pain: Moderate	5.3 (0.6 to 17.7)			
New or worsened muscle pain: Severe	0 (0.0 to 9.3)			
New or worsened muscle pain: Grade 4	0 (0.0 to 9.3)			
New or worsened joint pain: Any	2.6 (0.1 to 13.8)			
New or worsened joint pain: Mild	0 (0.0 to 9.3)			
New or worsened joint pain: Moderate	2.6 (0.1 to 13.8)			
New or worsened joint pain: Severe	0 (0.0 to 9.3)			
New or worsened joint pain: Grade 4	0 (0.0 to 9.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=2 to <5 Years of age

End point title	Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=2 to <5 Years of age[7]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation. Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	32		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	0 (0.0 to 20.6)	28.1 (13.7 to 46.7)		
Redness: Mild	0 (0.0 to 20.6)	25.0 (11.5 to 43.4)		
Redness: Moderate	0 (0.0 to 20.6)	3.1 (0.1 to 16.2)		
Redness: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Redness: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Swelling: Any	0 (0.0 to 20.6)	9.4 (2.0 to 25.0)		
Swelling: Mild	0 (0.0 to 20.6)	6.3 (0.8 to 20.8)		
Swelling: Moderate	0 (0.0 to 20.6)	3.1 (0.1 to 16.2)		
Swelling: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Swelling: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Pain at the injection site: Any	31.3 (11.0 to 58.7)	62.5 (43.7 to 78.9)		
Pain at the injection site: Mild	25.0 (7.3 to 52.4)	56.3 (37.7 to 73.6)		
Pain at the injection site: Moderate	6.3 (0.2 to 30.2)	6.3 (0.8 to 20.8)		
Pain at the injection site: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Pain at the injection site: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=2 to <5 Years of age

End point title	Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=2 to <5 Years of age[8]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation. Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	32		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	0 (0.0 to 20.6)	15.6 (5.3 to 32.8)		
Redness: Mild	0 (0.0 to 20.6)	15.6 (5.3 to 32.8)		
Redness: Moderate	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Redness: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Redness: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Swelling: Any	0 (0.0 to 20.6)	3.1 (0.1 to 16.2)		
Swelling: Mild	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Swelling: Moderate	0 (0.0 to 20.6)	3.1 (0.1 to 16.2)		
Swelling: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Swelling: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Pain at the injection site: Any	37.5 (15.2 to 64.6)	53.1 (34.7 to 70.9)		
Pain at the injection site: Mild	37.5 (15.2 to 64.6)	43.8 (26.4 to 62.3)		
Pain at the injection site: Moderate	0 (0.0 to 20.6)	9.4 (2.0 to 25.0)		
Pain at the injection site: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Pain at the injection site: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=2 to <5 Years of age

End point title	Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=2 to <5 Years of age[9]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation. Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 3 mcg)	Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 10 mcg)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	26	13		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	3.8 (0.1 to 19.6)	15.4 (1.9 to 45.4)		
Redness: Mild	3.8 (0.1 to 19.6)	15.4 (1.9 to 45.4)		
Redness: Moderate	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Redness: Severe	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Redness: Grade 4	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Swelling: Any	0 (0.0 to 13.2)	7.7 (0.2 to 36.0)		
Swelling: Mild	0 (0.0 to 13.2)	7.7 (0.2 to 36.0)		
Swelling: Moderate	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Swelling: Severe	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Swelling: Grade 4	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Pain at the injection site: Any	34.6 (17.2 to 55.7)	84.6 (54.6 to 98.1)		
Pain at the injection site: Mild	34.6 (17.2 to 55.7)	38.5 (13.9 to 68.4)		
Pain at the injection site: Moderate	0 (0.0 to 13.2)	38.5 (13.9 to 68.4)		
Pain at the injection site: Severe	0 (0.0 to 13.2)	7.7 (0.2 to 36.0)		
Pain at the injection site: Grade 4	0 (0.0 to 13.2)	0 (0.0 to 24.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=2 to <5 Years of age

End point title	Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=2 to <5 Years of age[10]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population was used.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	32		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 deg C	0 (0.0 to 20.6)	18.8 (7.2 to 36.4)		
Fever: 38.0 to 38.4 deg C	0 (0.0 to 20.6)	6.3 (0.8 to 20.8)		
Fever: >38.4 to 38.9 deg C	0 (0.0 to 20.6)	6.3 (0.8 to 20.8)		
Fever: >38.9 to 40.0 deg C	0 (0.0 to 20.6)	6.3 (0.8 to 20.8)		
Fever: >40.0 deg C	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Fatigue: Any	25.0 (7.3 to 52.4)	46.9 (29.1 to 65.3)		
Fatigue: Mild	18.8 (4.0 to 45.6)	34.4 (18.6 to 53.2)		
Fatigue: Moderate	6.3 (0.2 to 30.2)	12.5 (3.5 to 29.0)		
Fatigue: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Fatigue: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		

Headache: Any	12.5 (1.6 to 38.3)	9.4 (2.0 to 25.0)		
Headache: Mild	6.3 (0.2 to 30.2)	6.3 (0.8 to 20.8)		
Headache: Moderate	6.3 (0.2 to 30.2)	3.1 (0.1 to 16.2)		
Headache: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Headache: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Chills: Any	6.3 (0.2 to 30.2)	6.3 (0.8 to 20.8)		
Chills: Mild	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Chills: Moderate	6.3 (0.2 to 30.2)	6.3 (0.8 to 20.8)		
Chills: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Chills: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Vomiting: Any	0 (0.0 to 20.6)	3.1 (0.1 to 16.2)		
Vomiting: Mild	0 (0.0 to 20.6)	3.1 (0.1 to 16.2)		
Vomiting: Moderate	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Vomiting: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Vomiting: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Diarrhea: Any	6.3 (0.2 to 30.2)	6.3 (0.8 to 20.8)		
Diarrhea: Mild	6.3 (0.2 to 30.2)	6.3 (0.8 to 20.8)		
Diarrhea: Moderate	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Diarrhea: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Diarrhea: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
New or worsened muscle pain: Any	0 (0.0 to 20.6)	6.3 (0.8 to 20.8)		
New or worsened muscle pain: Mild	0 (0.0 to 20.6)	3.1 (0.1 to 16.2)		
New or worsened muscle pain: Moderate	0 (0.0 to 20.6)	3.1 (0.1 to 16.2)		
New or worsened muscle pain: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
New or worsened muscle pain: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
New or worsened joint pain: Any	6.3 (0.2 to 30.2)	0 (0.0 to 10.9)		
New or worsened joint pain: Mild	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
New or worsened joint pain: Moderate	6.3 (0.2 to 30.2)	0 (0.0 to 10.9)		
New or worsened joint pain: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
New or worsened joint pain: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=2 to <5 Years of age

End point title	Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=2 to <5 Years of age[11]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C.Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population was used.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	32		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 deg C	6.3 (0.2 to 30.2)	18.8 (7.2 to 36.4)		
Fever: 38.0 to 38.4 deg C	0 (0.0 to 20.6)	9.4 (2.0 to 25.0)		
Fever: >38.4 to 38.9 deg C	6.3 (0.2 to 30.2)	3.1 (0.1 to 16.2)		
Fever: >38.9 to 40.0 deg C	0 (0.0 to 20.6)	6.3 (0.8 to 20.8)		
Fever: >40.0 deg C	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Fatigue: Any	25.0 (7.3 to 52.4)	59.4 (40.6 to 76.3)		
Fatigue: Mild	12.5 (1.6 to 38.3)	31.3 (16.1 to 50.0)		
Fatigue: Moderate	12.5 (1.6 to 38.3)	28.1 (13.7 to 46.7)		
Fatigue: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Fatigue: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Headache: Any	12.5 (1.6 to 38.3)	15.6 (5.3 to 32.8)		
Headache: Mild	6.3 (0.2 to 30.2)	9.4 (2.0 to 25.0)		
Headache: Moderate	6.3 (0.2 to 30.2)	6.3 (0.8 to 20.8)		
Headache: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Headache: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Chills: Any	6.3 (0.2 to 30.2)	6.3 (0.8 to 20.8)		
Chills: Mild	0 (0.0 to 20.6)	6.3 (0.8 to 20.8)		
Chills: Moderate	6.3 (0.2 to 30.2)	0 (0.0 to 10.9)		
Chills: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Chills: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		

Vomiting: Any	6.3 (0.2 to 30.2)	6.3 (0.8 to 20.8)		
Vomiting: Mild	6.3 (0.2 to 30.2)	3.1 (0.1 to 16.2)		
Vomiting: Moderate	0 (0.0 to 20.6)	3.1 (0.1 to 16.2)		
Vomiting: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Vomiting: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Diarrhea: Any	6.3 (0.2 to 30.2)	12.5 (3.5 to 29.0)		
Diarrhea: Mild	6.3 (0.2 to 30.2)	12.5 (3.5 to 29.0)		
Diarrhea: Moderate	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Diarrhea: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
Diarrhea: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
New or worsened muscle pain: Any	0 (0.0 to 20.6)	9.4 (2.0 to 25.0)		
New or worsened muscle pain: Mild	0 (0.0 to 20.6)	6.3 (0.8 to 20.8)		
New or worsened muscle pain: Moderate	0 (0.0 to 20.6)	3.1 (0.1 to 16.2)		
New or worsened muscle pain: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
New or worsened muscle pain: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
New or worsened joint pain: Any	0 (0.0 to 20.6)	3.1 (0.1 to 16.2)		
New or worsened joint pain: Mild	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
New or worsened joint pain: Moderate	0 (0.0 to 20.6)	3.1 (0.1 to 16.2)		
New or worsened joint pain: Severe	0 (0.0 to 20.6)	0 (0.0 to 10.9)		
New or worsened joint pain: Grade 4	0 (0.0 to 20.6)	0 (0.0 to 10.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=2 to <5 Years of age

End point title	Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=2 to <5 Years of age[12]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C.Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population was used.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 3 mcg)	Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 10 mcg)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	26	13		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 deg C	0 (0.0 to 13.2)	15.4 (1.9 to 45.4)		
Fever: 38.0 to 38.4 deg C	0 (0.0 to 13.2)	7.7 (0.2 to 36.0)		
Fever: >38.4 to 38.9 deg C	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Fever: >38.9 to 40.0 deg C	0 (0.0 to 13.2)	7.7 (0.2 to 36.0)		
Fever: >40.0 deg C	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Fatigue: Any	30.8 (14.3 to 51.8)	53.8 (25.1 to 80.8)		
Fatigue: Mild	19.2 (6.6 to 39.4)	23.1 (5.0 to 53.8)		
Fatigue: Moderate	11.5 (2.4 to 30.2)	30.8 (9.1 to 61.4)		
Fatigue: Severe	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Fatigue: Grade 4	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Headache: Any	3.8 (0.1 to 19.6)	23.1 (5.0 to 53.8)		
Headache: Mild	3.8 (0.1 to 19.6)	15.4 (1.9 to 45.4)		
Headache: Moderate	0 (0.0 to 13.2)	7.7 (0.2 to 36.0)		
Headache: Severe	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Headache: Grade 4	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Chills: Any	0 (0.0 to 13.2)	15.4 (1.9 to 45.4)		
Chills: Mild	0 (0.0 to 13.2)	7.7 (0.2 to 36.0)		
Chills: Moderate	0 (0.0 to 13.2)	7.7 (0.2 to 36.0)		
Chills: Severe	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Chills: Grade 4	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Vomiting: Any	0 (0.0 to 13.2)	23.1 (5.0 to 53.8)		
Vomiting: Mild	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Vomiting: Moderate	0 (0.0 to 13.2)	23.1 (5.0 to 53.8)		
Vomiting: Severe	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Vomiting: Grade 4	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Diarrhea: Any	3.8 (0.1 to 19.6)	7.7 (0.2 to 36.0)		
Diarrhea: Mild	3.8 (0.1 to 19.6)	7.7 (0.2 to 36.0)		
Diarrhea: Moderate	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
Diarrhea: Severe	0 (0.0 to 13.2)	0 (0.0 to 24.7)		

Diarrhea: Grade 4	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
New or worsened muscle pain: Any	0 (0.0 to 13.2)	15.4 (1.9 to 45.4)		
New or worsened muscle pain: Mild	0 (0.0 to 13.2)	7.7 (0.2 to 36.0)		
New or worsened muscle pain: Moderate	0 (0.0 to 13.2)	7.7 (0.2 to 36.0)		
New or worsened muscle pain: Severe	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
New or worsened muscle pain: Grade 4	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
New or worsened joint pain: Any	0 (0.0 to 13.2)	7.7 (0.2 to 36.0)		
New or worsened joint pain: Mild	0 (0.0 to 13.2)	7.7 (0.2 to 36.0)		
New or worsened joint pain: Moderate	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
New or worsened joint pain: Severe	0 (0.0 to 13.2)	0 (0.0 to 24.7)		
New or worsened joint pain: Grade 4	0 (0.0 to 13.2)	0 (0.0 to 24.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=6 Months to <2 Years of age

End point title	Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=6 Months to <2 Years of age[13]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)&Grade (G) 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]).Tenderness at injection site was graded as mild(hurts if gently touched),moderate(hurts if gently touched with crying),severe(causes limitation of limb movement)&G4 ER visit or hospitalisation.G4 were classified by investigator or medically qualified person.Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	18.8 (4.0 to 45.6)			
Redness: Mild	18.8 (4.0 to 45.6)			

Redness: Moderate	0 (0.0 to 20.6)			
Redness: Severe	0 (0.0 to 20.6)			
Redness: Grade 4	0 (0.0 to 20.6)			
Swelling: Any	6.3 (0.2 to 30.2)			
Swelling: Mild	6.3 (0.2 to 30.2)			
Swelling: Moderate	0 (0.0 to 20.6)			
Swelling: Severe	0 (0.0 to 20.6)			
Swelling: Grade 4	0 (0.0 to 20.6)			
Tenderness at the injection site: Any	0 (0.0 to 20.6)			
Tenderness at the injection site: Mild	0 (0.0 to 20.6)			
Tenderness at the injection site: Moderate	0 (0.0 to 20.6)			
Tenderness at the injection site: Severe	0 (0.0 to 20.6)			
Tenderness at the injection site: Grade 4	0 (0.0 to 20.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=6 Months to <2 Years of age

End point title	Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=6 Months to <2 Years of age[14]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)&Grade (G) 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]).Tenderness at injection site was graded as mild(hurts if gently touched),moderate(hurts if gently touched with crying),severe(causes limitation of limb movement)&G4 ER visit or hospitalisation.G4 were classified by investigator or medically qualified person.Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	0 (0.0 to 20.6)			
Redness: Mild	0 (0.0 to 20.6)			

Redness: Moderate	0 (0.0 to 20.6)			
Redness: Severe	0 (0.0 to 20.6)			
Redness: Grade 4	0 (0.0 to 20.6)			
Swelling: Any	0 (0.0 to 20.6)			
Swelling: Mild	0 (0.0 to 20.6)			
Swelling: Moderate	0 (0.0 to 20.6)			
Swelling: Severe	0 (0.0 to 20.6)			
Swelling: Grade 4	0 (0.0 to 20.6)			
Tenderness at the injection site: Any	6.3 (0.2 to 30.2)			
Tenderness at the injection site: Mild	6.3 (0.2 to 30.2)			
Tenderness at the injection site: Moderate	0 (0.0 to 20.6)			
Tenderness at the injection site: Severe	0 (0.0 to 20.6)			
Tenderness at the injection site: Grade 4	0 (0.0 to 20.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=6 Months to <2 Years of age

End point title	Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=6 Months to <2 Years of age[15]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)&G4(necrosis [redness and swelling] or exfoliative dermatitis [redness]).Tenderness at injection site was graded as mild(hurts if gently touched),moderate(hurts if gently touched with crying),severe(causes limitation of limb movement)&G4 ER visit or hospitalisation for severe tenderness at injection site).G4 were classified by investigator or medically qualified person.Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention. 'N'= participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: Percentage of participants				
number (confidence interval 95%)				

Redness: Any	13.3 (1.7 to 40.5)			
Redness: Mild	13.3 (1.7 to 40.5)			
Redness: Moderate	0 (0.0 to 21.8)			
Redness: Severe	0 (0.0 to 21.8)			
Redness: Grade 4	0 (0.0 to 21.8)			
Swelling: Any	6.7 (0.2 to 31.9)			
Swelling: Mild	6.7 (0.2 to 31.9)			
Swelling: Moderate	0 (0.0 to 21.8)			
Swelling: Severe	0 (0.0 to 21.8)			
Swelling: Grade 4	0 (0.0 to 21.8)			
Tenderness at the injection site: Any	26.7 (7.8 to 55.1)			
Tenderness at the injection site: Mild	26.7 (7.8 to 55.1)			
Tenderness at the injection site: Moderate	0 (0.0 to 21.8)			
Tenderness at the injection site: Severe	0 (0.0 to 21.8)			
Tenderness at the injection site: Grade 4	0 (0.0 to 21.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=6 Months to <2 Years of age

End point title	Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=6 Months to <2 Years of age[16]

End point description:

Systemic events recorded in an e-diary and at unscheduled clinical assessments from Day 1 to 7 after Dose 1.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C.Decreased appetite: mild (decreased interest in eating), moderate (decreased oral intake),severe (refusal to feed).Drowsiness: mild (increased or prolonged sleeping bouts), moderate (slightly subdued interfering with daily activity), severe (disabling; not interested in usual daily activity).Irritability: mild (easily consolable), moderate(requiring increased attention),severe(Inconsolable; crying cannot be comforted).G4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population was used.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[16] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0	6.3 (0.2 to 30.2)			
Fever: 38.0 to 38.4 deg C	6.3 (0.2 to 30.2)			
Fever: >38.4 to 38.9 deg C	0 (0.0 to 20.6)			
Fever: >38.9 to 40.0 deg C	0 (0.0 to 20.6)			
Fever: >40.0 deg C	0 (0.0 to 20.6)			
Decreased appetite: Any	6.3 (0.2 to 30.2)			
Decreased appetite: Mild	0 (0.0 to 20.6)			
Decreased appetite: Moderate	6.3 (0.2 to 30.2)			
Decreased appetite: Severe	0 (0.0 to 20.6)			
Decreased appetite: Grade 4	0 (0.0 to 20.6)			
Drowsiness: Any	25.0 (7.3 to 52.4)			
Drowsiness: Mild	18.8 (4.0 to 45.6)			
Drowsiness: Moderate	6.3 (0.2 to 30.2)			
Drowsiness: Severe	0 (0.0 to 20.6)			
Drowsiness: Grade 4	0 (0.0 to 20.6)			
Irritability: Any	43.8 (19.8 to 70.1)			
Irritability: Mild	18.8 (4.0 to 45.6)			
Irritability: Moderate	25.0 (7.3 to 52.4)			
Irritability: Severe	0 (0.0 to 20.6)			
Irritability: Grade 4	0 (0.0 to 20.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=6 Months to <2 Years of age

End point title	Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=6 Months to <2 Years of age[17]

End point description:

Systemic events recorded in an e-diary and at unscheduled clinical assessments from Day 1 to 7 after Dose 2.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C.Decreased appetite: mild (decreased interest in eating), moderate (decreased oral intake),severe (refusal to feed).Drowsiness: mild (increased or prolonged sleeping bouts), moderate (slightly subdued interfering with daily activity), severe (disabling; not interested in usual daily activity).Irritability: mild (easily consolable), moderate(requiring increased attention),severe(Inconsolable; crying cannot be comforted).G4 for all events: ER visit/hospitalisation

and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population was used.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0	12.5 (1.6 to 38.3)			
Fever: 8.0 to 38.4 deg C	12.5 (1.6 to 38.3)			
Fever: >38.4 to 38.9 deg C	0 (0.0 to 20.6)			
Fever: >38.9 to 40.0 deg C	0 (0.0 to 20.6)			
Fever: >40.0 deg C	0 (0.0 to 20.6)			
Decreased appetite: Any	12.5 (1.6 to 38.3)			
Decreased appetite: Mild	12.5 (1.6 to 38.3)			
Decreased appetite: Moderate	0 (0.0 to 20.6)			
Decreased appetite: Severe	0 (0.0 to 20.6)			
Decreased appetite: Grade 4	0 (0.0 to 20.6)			
Drowsiness: Any	6.3 (0.2 to 30.2)			
Drowsiness: Mild	6.3 (0.2 to 30.2)			
Drowsiness: Moderate	0 (0.0 to 20.6)			
Drowsiness: Severe	0 (0.0 to 20.6)			
Drowsiness: Grade 4	0 (0.0 to 20.6)			
Irritability: Any	31.3 (11.0 to 58.7)			
Irritability: Mild	31.3 (11.0 to 58.7)			
Irritability: Moderate	0 (0.0 to 20.6)			
Irritability: Severe	0 (0.0 to 20.6)			
Irritability: Grade 4	0 (0.0 to 20.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days

After Dose 3: >=6 Months to <2 Years of age

End point title	Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=6 Months to <2 Years of age[18]

End point description:

Systemic events recorded in an e-diary and at unscheduled clinical assessments from Day 1 to 7 after Dose 3. Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Decreased appetite: mild (decreased interest in eating), moderate (decreased oral intake),severe (refusal to feed).Drowsiness: mild (increased or prolonged sleeping bouts), moderate (slightly subdued interfering with daily activity), severe (disabling; not interested in usual daily activity).Irritability: mild (easily consolable), moderate(requiring increased attention),severe(Inconsolable; crying cannot be comforted).G4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population was used.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0	6.7 (0.2 to 31.9)			
Fever: 38.0 to 38.4 deg C	0 (0.0 to 21.8)			
Fever: >38.4 to 38.9 deg C	0 (0.0 to 21.8)			
Fever: >38.9 to 40.0 deg C	6.7 (0.2 to 31.9)			
Fever: >40.0 deg C	0 (0.0 to 21.8)			
Decreased appetite: Any	13.3 (1.7 to 40.5)			
Decreased appetite: Mild	6.7 (0.2 to 31.9)			
Decreased appetite: Moderate	6.7 (0.2 to 31.9)			
Decreased appetite: Severe	0 (0.0 to 21.8)			
Decreased appetite: Grade 4	0 (0.0 to 21.8)			
Drowsiness: Any	6.7 (0.2 to 31.9)			
Drowsiness: Mild	0 (0.0 to 21.8)			
Drowsiness: Moderate	6.7 (0.2 to 31.9)			
Drowsiness: Severe	0 (0.0 to 21.8)			
Drowsiness: Grade 4	0 (0.0 to 21.8)			
Irritability: Any	26.7 (7.8 to 55.1)			
Irritability: Mild	13.3 (1.7 to 40.5)			
Irritability: Moderate	13.3 (1.7 to 40.5)			

Irritability: Severe	0 (0.0 to 21.8)			
Irritability: Grade 4	0 (0.0 to 21.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=5 to <12 Years of age

End point title	Phase 1: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=5 to <12 Years of age[19]

End point description:

An adverse event (AE) was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 1 to 1 month after dose 2 were reported in this endpoint. Exact 2-sided 95% CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 1 to 1 month after Dose 2

Notes:

[19] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age	Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age	Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	4	12
Units: Percentage of participants				
number (confidence interval 95%)	43.8 (19.8 to 70.1)	31.3 (11.0 to 58.7)	50.0 (6.8 to 93.2)	25.0 (5.5 to 57.2)

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: >=5 to <12 Years of age

End point title	Phase 1: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: >=5 to <12 Years of age[20]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study

intervention. Percentage of participants reporting AEs after dose 3 to 1 month after dose 3 were reported in this endpoint. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Exact 2-sided 95% CI based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 3 to 1 month after Dose 3

Notes:

[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: 5 to <12 Years BNT162b2 10 mcg			
Subject group type	Subject analysis set			
Number of subjects analysed	38			
Units: Percentage of participants				
number (confidence interval 95%)	15.8 (6.0 to 31.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: >=5 to <12 Years of age

End point title	Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: >=5 to <12 Years of age[21]

End point description:

A serious adverse event (SAE) was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic.Exact 2-sided 95% CI based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 1 to 6 months after Dose 2

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age	Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age	Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	4	12
Units: Percentage of participants				

number (confidence interval 95%)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: >=2 to <5 Years of age

End point title	Phase 1: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: >=2 to <5 Years of age[22]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention.Exact 2-sided 95% CI based on the Clopper and Pearson method. Percentage of participants reporting AEs after dose 3 to 1 month after dose 3 were reported in this endpoint. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 3 to 1 month after Dose 3

Notes:

[22] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 3 mcg)	Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 10 mcg)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	27	13		
Units: Percentage of participants				
number (confidence interval 95%)	11.1 (2.4 to 29.2)	0 (0.0 to 24.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=2 to <5 Years of age

End point title	Phase 1: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=2 to <5 Years of age[23]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 1 to 1 month after dose 2 were

reported in this endpoint. Exact 2-sided 95% CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 1 to 1 month after Dose 2

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	32		
Units: Percentage of participants				
number (confidence interval 95%)	25.0 (7.3 to 52.4)	37.5 (21.1 to 56.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: >=5 to <12 Years of age

End point title	Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: >=5 to <12 Years of age[24]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic Exact 2-sided 95% CI based on the Clopper and Pearson method.Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 3 to 6 Months after Dose 3 (Approximately 6 months)

Notes:

[24] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: 5 to <12 Years BNT162b2 10 mcg			
Subject group type	Subject analysis set			
Number of subjects analysed	38			
Units: Percentage of participants				
number (confidence interval 95%)	0 (0 to 0)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=6 Months to <2 Years of age

End point title	Phase 1: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=6 Months to <2 Years of age[25]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 1 to 1 month after dose 2 were reported in this endpoint. Exact 2-sided 95% CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From dose 1 to 1 month after dose 2

Notes:

[25] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Percentage of participants				
number (confidence interval 95%)	12.5 (1.6 to 38.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: >=2 to <5 Years of age

End point title	Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: >=2 to <5 Years of age[26]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect;

was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From dose 3 to 6 months after dose 3 (Approximately 6 months)

Notes:

[26] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 3 mcg)	Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 10 mcg)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	27	13		
Units: Percentage of participants				
number (confidence interval 95%)	0 (0 to 0)	0 (0 to 0)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: >=2 to <5 Years of age

End point title	Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: >=2 to <5 Years of age[27]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI based on the Clopper and Pearson method.Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 1 to 6 months after Dose 2

Notes:

[27] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	32		
Units: Percentage of participants				
number (confidence interval 95%)	0 (0 to 0)	0 (0 to 0)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: >=6 Months to <2 Years of age

End point title	Phase 1: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: >=6 Months to <2 Years of age[28]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 3 to 1 month after dose 3 were reported in this endpoint. Exact 2-sided 95% CI based on the Clopper and Pearson method.Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention. 'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From dose 3 to 1 month after dose 3

Notes:

[28] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: Percentage of participants				
number (confidence interval 95%)	6.7 (0.2 to 31.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: >=6 Months to <2 Years of age

End point title	Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: >=6 Months to <2 Years of age[29]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect;

was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic.Exact 2-sided 95% CI based on the Clopper and Pearson method.Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 1 to 6 months after Dose 2

Notes:

[29] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Percentage of participants				
number (confidence interval 95%)	0 (0 to 0)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: >=6 Months to <2 Years of age

End point title	Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: >=6 Months to <2 Years of age[30]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic.Exact 2-sided 95% CI based on the Clopper and Pearson method.Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From dose 3 to 6 months after dose 3 (Approximately 6 months)

Notes:

[30] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age			
Subject group type	Reporting group			
Number of subjects analysed	15			
Units: Percentage of participants				
number (confidence interval 95%)	0 (0 to 0)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1:Troponin Group: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1:Troponin Group: >=5 to <12 Years of age[31]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild >2.0 to 5.0 cm),moderate (>5.0 to 10.0), severe >10.0 cm) and G4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and G4 ER visit or hospitalisation for severe pain at injection site). G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention. 'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[31] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years	Phase 2/3:Troponin group:Placebo:5 to <12 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	515	260		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	15.5 (12.5 to 19.0)	6.2 (3.6 to 9.8)		
Redness: Mild	11.8 (9.2 to 15.0)	5.4 (3.0 to 8.9)		
Redness: Moderate	3.7 (2.2 to 5.7)	0.4 (0.0 to 2.1)		
Redness: Severe	0 (0.0 to 0.7)	0.4 (0.0 to 2.1)		
Redness: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 1.4)		
Swelling: Any	10.9 (8.3 to 13.9)	4.6 (2.4 to 7.9)		
Swelling: Mild	7.6 (5.4 to 10.2)	2.7 (1.1 to 5.5)		
Swelling: Moderate	3.3 (1.9 to 5.2)	1.9 (0.6 to 4.4)		
Swelling: Severe	0 (0.0 to 0.7)	0 (0.0 to 1.4)		

Swelling: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 1.4)		
Pain at the injection site: Any	72.4 (68.3 to 76.2)	28.1 (22.7 to 34.0)		
Pain at the injection site: Mild	57.7 (53.3 to 62.0)	23.5 (18.4 to 29.1)		
Pain at the injection site: Moderate	14.8 (11.8 to 18.1)	4.6 (2.4 to 7.9)		
Pain at the injection site: Severe	0 (0.0 to 0.7)	0 (0.0 to 1.4)		
Pain at the injection site: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 1.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: Troponin Group: >=12 to <16 Years of age

End point title	Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: Troponin Group: >=12 to <16 Years of age[32]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild >2.0 to 5.0 cm),moderate (>5.0 to 10.0), severe >10.0 cm) and G4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and G4 ER visit or hospitalisation for severe pain at injection site). G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention. 'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[32] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162b2 (30 mcg):12 to <16 years			
Subject group type	Reporting group			
Number of subjects analysed	475			
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	2.1 (1.0 to 3.8)			
Redness: Mild	1.5 (0.6 to 3.0)			
Redness: Moderate	0.6 (0.1 to 1.8)			
Redness: Severe	0 (0.0 to 0.8)			
Redness: Grade 4	0 (0.0 to 0.8)			
Swelling: Any	4.4 (2.8 to 6.7)			
Swelling: Mild	2.7 (1.5 to 4.6)			

Swelling: Moderate	1.7 (0.7 to 3.3)			
Swelling: Severe	0 (0.0 to 0.8)			
Swelling: Grade 4	0 (0.0 to 0.8)			
Pain at the injection site: Any	72.4 (68.2 to 76.4)			
Pain at the injection site: Mild	43.8 (39.3 to 48.4)			
Pain at the injection site: Moderate	28.2 (24.2 to 32.5)			
Pain at the injection site: Severe	0.4 (0.1 to 1.5)			
Pain at the injection site: Grade 4	0 (0.0 to 0.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: Troponin Group: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: Troponin Group: >=5 to <12 Years of age[33]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention. 'N'= participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[33] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years	Phase 2/3:Troponin group:Placebo: 5 to <12 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	497	107		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	16.7 (13.5 to 20.3)	1.9 (0.2 to 6.6)		
Redness: Mild	9.9 (7.4 to 12.8)	1.9 (0.2 to 6.6)		
Redness: Moderate	6.8 (4.8 to 9.4)	0 (0.0 to 3.4)		
Redness: Severe	0 (0.0 to 0.7)	0 (0.0 to 3.4)		

Redness: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 3.4)		
Swelling: Any	11.5 (8.8 to 14.6)	4.7 (1.5 to 10.6)		
Swelling: Mild	6.8 (4.8 to 9.4)	2.8 (0.6 to 8.0)		
Swelling: Moderate	4.6 (3.0 to 6.9)	1.9 (0.2 to 6.6)		
Swelling: Severe	0 (0.0 to 0.7)	0 (0.0 to 3.4)		
Swelling: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 3.4)		
Pain at the injection site: Any	66.8 (62.5 to 70.9)	23.4 (15.7 to 32.5)		
Pain at the injection site: Mild	48.3 (43.8 to 52.8)	19.6 (12.6 to 28.4)		
Pain at the injection site: Moderate	18.5 (15.2 to 22.2)	3.7 (1.0 to 9.3)		
Pain at the injection site: Severe	0 (0.0 to 0.7)	0 (0.0 to 3.4)		
Pain at the injection site: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 3.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: Troponin Group: >=12 to <16 Years of age

End point title	Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: Troponin Group: >=12 to <16 Years of age[34]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild >2.0 to 5.0 cm),moderate (>5.0 to 10.0), severe >10.0 cm) and G4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and G4 ER visit or hospitalisation for severe pain at injection site). G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention. 'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[34] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162b2 (30 mcg):12 to <16 years			
Subject group type	Reporting group			
Number of subjects analysed	448			
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	0.9 (0.2 to 2.3)			

Redness: Mild	0.4 (0.1 to 1.6)			
Redness: Moderate	0.2 (0.0 to 1.2)			
Redness: Severe	0.2 (0.0 to 1.2)			
Redness: Grade 4	0 (0.0 to 0.8)			
Swelling: Any	1.8 (0.8 to 3.5)			
Swelling: Mild	0.9 (0.2 to 2.3)			
Swelling: Moderate	0.9 (0.2 to 2.3)			
Swelling: Severe	0 (0.0 to 0.8)			
Swelling: Grade 4	0 (0.0 to 0.8)			
Pain at the injection site: Any	57.8 (53.1 to 62.4)			
Pain at the injection site: Mild	36.6 (32.1 to 41.3)			
Pain at the injection site: Moderate	20.8 (17.1 to 24.8)			
Pain at the injection site: Severe	0.4 (0.1 to 1.6)			
Pain at the injection site: Grade 4	0 (0.0 to 0.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: Troponin Group: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: Troponin Group: >=5 to <12 Years of age[35]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention. 'N'= participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[35] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years	Phase 2/3:Troponin group:Placebo:5 to <12 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	394	0[36]		
Units: Percentage of participants				

number (confidence interval 95%)				
Redness: Any	17.0 (13.4 to 21.1)	(to)		
Redness: Mild	11.2 (8.2 to 14.7)	(to)		
Redness: Moderate	5.8 (3.7 to 8.6)	(to)		
Redness: Severe	0 (0.0 to 0.9)	(to)		
Redness: Grade 4	0 (0.0 to 0.9)	(to)		
Swelling: Any	12.7 (9.6 to 16.4)	(to)		
Swelling: Mild	9.4 (6.7 to 12.7)	(to)		
Swelling: Moderate	3.3 (1.8 to 5.6)	(to)		
Swelling: Severe	0 (0.0 to 0.9)	(to)		
Swelling: Grade 4	0 (0.0 to 0.9)	(to)		
Pain at the injection site: Any	69.3 (64.5 to 73.8)	(to)		
Pain at the injection site: Mild	48.0 (42.9 to 53.0)	(to)		
Pain at the injection site: Moderate	20.8 (16.9 to 25.2)	(to)		
Pain at the injection site: Severe	0.5 (0.1 to 1.8)	(to)		
Pain at the injection site: Grade 4	0 (0.0 to 0.9)	(to)		

Notes:

[36] - No participants received dose 3 from this cohort.

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: Troponin Group: >=12 to <16 Years of age

End point title	Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: Troponin Group: >=12 to <16 Years of age[37]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild >2.0 to 5.0 cm),moderate (>5.0 to 10.0), severe >10.0 cm) and G4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and G4 ER visit or hospitalisation for severe pain at injection site). G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention. 'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[37] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162 b2 (30 mcg):12 to <16 years			
Subject group type	Reporting group			
Number of subjects analysed	405			
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	3.5 (1.9 to 5.7)			
Redness: Mild	3.0 (1.5 to 5.1)			
Redness: Moderate	0.5 (0.1 to 1.8)			
Redness: Severe	0 (0.0 to 0.9)			
Redness: Grade 4	0 (0.0 to 0.9)			
Swelling: Any	3.0 (1.5 to 5.1)			
Swelling: Mild	2.0 (0.9 to 3.9)			
Swelling: Moderate	1.0 (0.3 to 2.5)			
Swelling: Severe	0 (0.0 to 0.9)			
Swelling: Grade 4	0 (0.0 to 0.9)			
Pain at the injection site: Any	63.5 (58.6 to 68.2)			
Pain at the injection site: Mild	35.8 (31.1 to 40.7)			
Pain at the injection site: Moderate	27.4 (23.1 to 32.0)			
Pain at the injection site: Severe	0.2 (0.0 to 1.4)			
Pain at the injection site: Grade 4	0 (0.0 to 0.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1:Troponin Group: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1:Troponin Group: >=5 to <12 Years of age[38]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from upto Day 7 after Dose 1.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild:1-2 times in 24 hours,moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24 hours, moderate:4-5 loose stools in 24 hours,severe: 6 or more loose stools in 24 hours.Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95% CI based on Clopper and Pearson method.Safety population.'N'= participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[38] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years	Phase 2/3:Troponin group:Placebo:5 to <12 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	515	260		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >= 38.0	1.4 (0.5 to 2.8)	3.1 (1.3 to 6.0)		
Fever: 38.0 to 38.4 deg C	0.8 (0.2 to 2.0)	1.9 (0.6 to 4.4)		
Fever: >38.4 to 38.9 deg C	0.6 (0.1 to 1.7)	1.2 (0.2 to 3.3)		
Fever: >38.9 to 40.0 deg C	0 (0.0 to 0.7)	0 (0.0 to 1.4)		
Fever: >40.0 deg C	0 (0.0 to 0.7)	0 (0.0 to 1.4)		
Fatigue: Any	37.1 (32.9 to 41.4)	37.7 (31.8 to 43.9)		
Fatigue: Mild	24.1 (20.4 to 28.0)	23.8 (18.8 to 29.5)		
Fatigue: Moderate	13.0 (10.2 to 16.2)	13.1 (9.2 to 17.8)		
Fatigue: Severe	0 (0.0 to 0.7)	0.8 (0.1 to 2.8)		
Fatigue: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 1.4)		
Headache: Any	25.4 (21.7 to 29.4)	25.8 (20.6 to 31.5)		
Headache: Mild	18.3 (15.0 to 21.9)	19.2 (14.6 to 24.6)		
Headache: Moderate	6.8 (4.8 to 9.3)	6.5 (3.9 to 10.3)		
Headache: Severe	0.4 (0.0 to 1.4)	0 (0.0 to 1.4)		
Headache: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 1.4)		
Chills: Any	7.2 (5.1 to 9.8)	9.6 (6.3 to 13.9)		
Chills: Mild	5.6 (3.8 to 8.0)	6.5 (3.9 to 10.3)		
Chills: Moderate	1.4 (0.5 to 2.8)	3.1 (1.3 to 6.0)		
Chills: Severe	0.2 (0.0 to 1.1)	0 (0.0 to 1.4)		
Chills: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 1.4)		
Vomiting: Any	1.7 (0.8 to 3.3)	2.3 (0.9 to 5.0)		
Vomiting: Mild	1.6 (0.7 to 3.0)	1.9 (0.6 to 4.4)		
Vomiting: Moderate	0.2 (0.0 to 1.1)	0.4 (0.0 to 2.1)		
Vomiting: Severe	0 (0.0 to 0.7)	0 (0.0 to 1.4)		
Vomiting: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 1.4)		
Diarrhea: Any	6.2 (4.3 to 8.7)	8.5 (5.4 to 12.5)		
Diarrhea: Mild	6.0 (4.1 to 8.4)	8.1 (5.1 to 12.1)		
Diarrhea: Moderate	0.2 (0.0 to 1.1)	0.4 (0.0 to 2.1)		
Diarrhea: Severe	0 (0.0 to 0.7)	0 (0.0 to 1.4)		
Diarrhea: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 1.4)		
New or worsened muscle pain: Any	11.7 (9.0 to 14.7)	10.0 (6.6 to 14.3)		

New or worsened muscle pain: Mild	8.2 (5.9 to 10.9)	7.7 (4.8 to 11.6)		
New or worsened muscle pain: Moderate	3.5 (2.1 to 5.5)	2.3 (0.9 to 5.0)		
New or worsened muscle pain: Severe	0 (0.0 to 0.7)	0 (0.0 to 1.4)		
New or worsened muscle pain: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 1.4)		
New or worsened joint pain: Any	5.2 (3.5 to 7.5)	6.9 (4.2 to 10.7)		
New or worsened joint pain: Mild	4.5 (2.9 to 6.6)	5.4 (3.0 to 8.9)		
New or worsened joint pain: Moderate	0.8 (0.2 to 2.0)	1.5 (0.4 to 3.9)		
New or worsened joint pain: Severe	0 (0.0 to 0.7)	0 (0.0 to 1.4)		
New or worsened joint pain: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 1.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: Troponin Group: >=12 to <16 Years of age

End point title	Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: Troponin Group: >=12 to <16 Years of age[39]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from upto Day 7 after Dose 1.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild:1-2 times in 24 hours,moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24 hours, moderate:4-5 loose stools in 24 hours,severe: 6 or more loose stools in 24 hours.Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95% CI based on Clopper and Pearson method.Safety population.'N'= participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[39] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162b2 (30 mcg):12 to <16 years			
Subject group type	Reporting group			
Number of subjects analysed	475			
Units: Percentage of participants				
number (confidence interval 95%)				
Fever:>=38.0	4.2 (2.6 to 6.4)			
Fever: 8.0 to 38.4 deg C	2.3 (1.2 to 4.1)			
Fever: >38.4 to 38.9 deg C	1.3 (0.5 to 2.7)			
Fever: >38.9 to 40.0 deg C	0.6 (0.1 to 1.8)			

Fever: >40.0 deg C	0 (0.0 to 0.8)			
Fatigue: Any	42.3 (37.8 to 46.9)			
Fatigue: Mild	26.3 (22.4 to 30.5)			
Fatigue: Moderate	15.6 (12.4 to 19.2)			
Fatigue: Severe	0.4 (0.1 to 1.5)			
Fatigue: Grade 4	0 (0.0 to 0.8)			
Headache: Any	33.3 (29.0 to 37.7)			
Headache: Mild	22.9 (19.2 to 27.0)			
Headache: Moderate	10.3 (7.7 to 13.4)			
Headache: Severe	0 (0.0 to 0.8)			
Headache: Grade 4	0 (0.0 to 0.8)			
Chills: Any	11.4 (8.7 to 14.6)			
Chills: Mild	8.6 (6.3 to 11.5)			
Chills: Moderate	2.5 (1.3 to 4.4)			
Chills: Severe	0.2 (0.0 to 1.2)			
Chills: Grade 4	0 (0.0 to 0.8)			
Vomiting: Any	2.9 (1.6 to 4.9)			
Vomiting: Mild	2.7 (1.5 to 4.6)			
Vomiting: Moderate	0.2 (0.0 to 1.2)			
Vomiting: Severe	0 (0.0 to 0.8)			
Vomiting: Grade 4	0 (0.0 to 0.8)			
Diarrhea: Any	9.1 (6.6 to 12.0)			
Diarrhea: Mild	6.9 (4.8 to 9.6)			
Diarrhea: Moderate	2.1 (1.0 to 3.8)			
Diarrhea: Severe	0 (0.0 to 0.8)			
Diarrhea: Grade 4	0 (0.0 to 0.8)			
New or worsened muscle pain: Any	26.3 (22.4 to 30.5)			
New or worsened muscle pain: Mild	14.7 (11.7 to 18.2)			
New or worsened muscle pain: Moderate	10.9 (8.3 to 14.1)			
New or worsened muscle pain: Severe	0.6 (0.1 to 1.8)			
New or worsened muscle pain: Grade 4	0 (0.0 to 0.8)			
New or worsened joint pain: Any	10.5 (7.9 to 13.6)			
New or worsened joint pain: Mild	5.1 (3.3 to 7.4)			
New or worsened joint pain: Moderate	5.5 (3.6 to 7.9)			
New or worsened joint pain: Severe	0 (0.0 to 0.8)			
New or worsened joint pain: Grade 4	0 (0.0 to 0.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2:Troponin Group: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2:Troponin Group: >=5 to <12 Years of age[40]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from upto Day 7 after Dose 2.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild:1-2 times in 24 hours,moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24 hours, moderate:4-5 loose stools in 24 hours,severe: 6 or more loose stools in 24 hours.Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95% CI based on Clopper and Pearson method.Safety population.'N'= participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[40] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years	Phase 2/3:Troponin group:Placebo:5 to <12 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	497	107		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0	5.0 (3.3 to 7.3)	0 (0.0 to 3.4)		
Fever:38.0 to 38.4 deg C	2.2 (1.1 to 3.9)	0 (0.0 to 3.4)		
Fever: >38.4 to 38.9 deg C	1.8 (0.8 to 3.4)	0 (0.0 to 3.4)		
Fever: >38.9 to 40.0 deg C	1.0 (0.3 to 2.3)	0 (0.0 to 3.4)		
Fever: >40.0 deg C	0 (0.0 to 0.7)	0 (0.0 to 3.4)		
Fatigue: Any	38.2 (33.9 to 42.7)	29.0 (20.6 to 38.5)		
Fatigue: Mild	22.5 (18.9 to 26.5)	15.9 (9.5 to 24.2)		
Fatigue: Moderate	15.5 (12.4 to 19.0)	13.1 (7.3 to 21.0)		
Fatigue: Severe	0.2 (0.0 to 1.1)	0 (0.0 to 3.4)		
Fatigue: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 3.4)		
Headache: Any	30.2 (26.2 to 34.4)	20.6 (13.4 to 29.5)		
Headache: Mild	20.1 (16.7 to 23.9)	14.0 (8.1 to 22.1)		
Headache: Moderate	9.9 (7.4 to 12.8)	6.5 (2.7 to 13.0)		
Headache: Severe	0.2 (0.0 to 1.1)	0 (0.0 to 3.4)		
Headache: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 3.4)		
Chills: Any	9.1 (6.7 to 11.9)	7.5 (3.3 to 14.2)		
Chills: Mild	5.8 (3.9 to 8.3)	6.5 (2.7 to 13.0)		

Chills: Moderate	3.2 (1.9 to 5.2)	0.9 (0.0 to 5.1)		
Chills: Severe	0 (0.0 to 0.7)	0 (0.0 to 3.4)		
Chills: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 3.4)		
Vomiting: Any	2.0 (1.0 to 3.7)	3.7 (1.0 to 9.3)		
Vomiting: Mild	1.8 (0.8 to 3.4)	2.8 (0.6 to 8.0)		
Vomiting: Moderate	0.2 (0.0 to 1.1)	0.9 (0.0 to 5.1)		
Vomiting: Severe	0 (0.0 to 0.7)	0 (0.0 to 3.4)		
Vomiting: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 3.4)		
Diarrhea: Any	7.4 (5.3 to 10.1)	5.6 (2.1 to 11.8)		
Diarrhea: Mild	7.0 (5.0 to 9.7)	5.6 (2.1 to 11.8)		
Diarrhea: Moderate	0.2 (0.0 to 1.1)	0 (0.0 to 3.4)		
Diarrhea: Severe	0.2 (0.0 to 1.1)	0 (0.0 to 3.4)		
Diarrhea: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 3.4)		
New or worsened muscle pain: Any	14.7 (11.7 to 18.1)	11.2 (5.9 to 18.8)		
New or worsened muscle pain: Mild	9.3 (6.9 to 12.2)	9.3 (4.6 to 16.5)		
New or worsened muscle pain: Moderate	5.4 (3.6 to 7.8)	1.9 (0.2 to 6.6)		
New or worsened muscle pain: Severe	0 (0.0 to 0.7)	0 (0.0 to 3.4)		
New or worsened muscle pain: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 3.4)		
New or worsened joint pain: Any	6.4 (4.4 to 9.0)	6.5 (2.7 to 13.0)		
New or worsened joint pain: Mild	4.2 (2.6 to 6.4)	6.5 (2.7 to 13.0)		
New or worsened joint pain: Moderate	2.2 (1.1 to 3.9)	0 (0.0 to 3.4)		
New or worsened joint pain: Severe	0 (0.0 to 0.7)	0 (0.0 to 3.4)		
New or worsened joint pain: Grade 4	0 (0.0 to 0.7)	0 (0.0 to 3.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: Troponin group: >=12 to <16 Years of age

End point title	Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: Troponin group: >=12 to <16 Years of age[41]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from upto Day 7 after Dose 2.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild:1-2 times in 24 hours,moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24 hours, moderate:4-5 loose stools in 24 hours,severe: 6 or more loose stools in 24 hours.Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95% CI based on Clopper and Pearson method.Safety population.'N'= participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[41] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162 b2 (30 mcg):12 to <16 years			
Subject group type	Reporting group			
Number of subjects analysed	448			
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0	3.3 (1.9 to 5.5)			
Fever:38.0 to 38.4 deg C	1.6 (0.6 to 3.2)			
Fever: >38.4 to 38.9 deg C	1.3 (0.5 to 2.9)			
Fever: >38.9 to 40.0 deg C	0.4 (0.1 to 1.6)			
Fever: >40.0 deg C	0 (0.0 to 0.8)			
Fatigue: Any	36.4 (31.9 to 41.0)			
Fatigue: Mild	21.0 (17.3 to 25.1)			
Fatigue: Moderate	15.0 (11.8 to 18.6)			
Fatigue: Severe	0.4 (0.1 to 1.6)			
Fatigue: Grade 4	0 (0.0 to 0.8)			
Headache: Any	33.3 (28.9 to 37.8)			
Headache: Mild	19.4 (15.9 to 23.4)			
Headache: Moderate	13.2 (10.2 to 16.7)			
Headache: Severe	0.7 (0.1 to 1.9)			
Headache: Grade 4	0 (0.0 to 0.8)			
Chills: Any	11.2 (8.4 to 14.4)			
Chills: Mild	7.4 (5.1 to 10.2)			
Chills: Moderate	3.8 (2.2 to 6.0)			
Chills: Severe	0 (0.0 to 0.8)			
Chills: Grade 4	0 (0.0 to 0.8)			
Vomiting: Any	2.2 (1.1 to 4.1)			
Vomiting: Mild	2.0 (0.9 to 3.8)			
Vomiting: Moderate	0.2 (0.0 to 1.2)			
Vomiting: Severe	0 (0.0 to 0.8)			
Vomiting: Grade 4	0 (0.0 to 0.8)			
Diarrhea: Any	7.1 (4.9 to 9.9)			
Diarrhea: Mild	5.1 (3.3 to 7.6)			
Diarrhea: Moderate	1.8 (0.8 to 3.5)			
Diarrhea: Severe	0.2 (0.0 to 1.2)			
Diarrhea: Grade 4	0 (0.0 to 0.8)			
New or worsened muscle pain: Any	19.6 (16.1 to 23.6)			
New or worsened muscle pain: Mild	12.5 (9.6 to 15.9)			

New or worsened muscle pain: Moderate	6.9 (4.7 to 9.7)			
New or worsened muscle pain: Severe	0.2 (0.0 to 1.2)			
New or worsened muscle pain: Grade 4	0 (0.0 to 0.8)			
New or worsened joint pain: Any	6.7 (4.6 to 9.4)			
New or worsened joint pain: Mild	3.8 (2.2 to 6.0)			
New or worsened joint pain: Moderate	2.7 (1.4 to 4.6)			
New or worsened joint pain: Severe	0.2 (0.0 to 1.2)			
New or worsened joint pain: Grade 4	0 (0.0 to 0.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: Troponin Group: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: Troponin Group: >=5 to <12 Years of age[42]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from upto Day 7 after Dose 3.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild:1-2 times in 24 hours,moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24 hours, moderate:4-5 loose stools in 24 hours,severe: 6 or more loose stools in 24 hours.Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95% CI based on Clopper and Pearson method.Safety population.'N'= participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[42] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years	Phase 2/3:Troponin group:Placebo: 5 to <12 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	394	0[43]		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0	4.6 (2.7 to 7.1)	(to)		
Fever:38.0 to 38.4 deg C	2.5 (1.2 to 4.6)	(to)		
Fever: >38.4 to 38.9 deg C	1.0 (0.3 to 2.6)	(to)		
Fever: >38.9 to 40.0 deg C	1.0 (0.3 to 2.6)	(to)		
Fever: >40.0 deg C	0 (0.0 to 0.9)	(to)		
Fatigue: Any	38.8 (34.0 to 43.8)	(to)		

Fatigue: Mild	26.4 (22.1 to 31.0)	(to)		
Fatigue: Moderate	11.9 (8.9 to 15.5)	(to)		
Fatigue: Severe	0.5 (0.1 to 1.8)	(to)		
Fatigue: Grade 4	0 (0.0 to 0.9)	(to)		
Headache: Any	23.6 (19.5 to 28.1)	(to)		
Headache: Mild	16.2 (12.7 to 20.3)	(to)		
Headache: Moderate	6.9 (4.6 to 9.8)	(to)		
Headache: Severe	0.5 (0.1 to 1.8)	(to)		
Headache: Grade 4	0 (0.0 to 0.9)	(to)		
Chills: Any	8.9 (6.3 to 12.1)	(to)		
Chills: Mild	5.8 (3.7 to 8.6)	(to)		
Chills: Moderate	2.8 (1.4 to 4.9)	(to)		
Chills: Severe	0.3 (0.0 to 1.4)	(to)		
Chills: Grade 4	0 (0.0 to 0.9)	(to)		
Vomiting: Any	1.8 (0.7 to 3.6)	(to)		
Vomiting: Mild	1.5 (0.6 to 3.3)	(to)		
Vomiting: Moderate	0.3 (0.0 to 1.4)	(to)		
Vomiting: Severe	0 (0.0 to 0.9)	(to)		
Vomiting: Grade 4	0 (0.0 to 0.9)	(to)		
Diarrhea: Any	4.8 (2.9 to 7.4)	(to)		
Diarrhea: Mild	4.6 (2.7 to 7.1)	(to)		
Diarrhea: Moderate	0.3 (0.0 to 1.4)	(to)		
Diarrhea: Severe	0 (0.0 to 0.9)	(to)		
Diarrhea: Grade 4	0 (0.0 to 0.9)	(to)		
New or worsened muscle pain: Any	18.5 (14.8 to 22.7)	(to)		
New or worsened muscle pain: Mild	10.2 (7.4 to 13.6)	(to)		
New or worsened muscle pain: Moderate	8.4 (5.8 to 11.6)	(to)		
New or worsened muscle pain: Severe	0 (0.0 to 0.9)	(to)		
New or worsened muscle pain: Grade 4	0 (0.0 to 0.9)	(to)		
New or worsened joint pain: Any	5.8 (3.7 to 8.6)	(to)		
New or worsened joint pain: Mild	4.1 (2.3 to 6.5)	(to)		
New or worsened joint pain: Moderate	1.8 (0.7 to 3.6)	(to)		
New or worsened joint pain: Severe	0 (0.0 to 0.9)	(to)		
New or worsened joint pain: Grade 4	0 (0.0 to 0.9)	(to)		

Notes:

[43] - No participants received dose 3 from this cohort.

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: Troponin Group: >=12 to <16 Years of age

End point title	Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: Troponin Group: >=12 to <16 Years of age[44]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from upto Day 7 after Dose 3.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild:1-2 times in 24 hours,moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24 hours, moderate:4-5 loose stools in 24 hours,severe: 6 or more loose stools in 24 hours.Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95% CI based on Clopper and Pearson method.Safety population.'N'= participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[44] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162 b2 (30 mcg):12 to <16 years			
Subject group type	Reporting group			
Number of subjects analysed	405			
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0	3.5 (1.9 to 5.7)			
Fever: 8.0 to 38.4 deg C	1.7 (0.7 to 3.5)			
Fever: >38.4 to 38.9 deg C	1.2 (0.4 to 2.9)			
Fever: >38.9 to 40.0 deg C	0.5 (0.1 to 1.8)			
Fever: >40.0 deg C	0 (0.0 to 0.9)			
Fatigue: Any	36.8 (32.1 to 41.7)			
Fatigue: Mild	21.7 (17.8 to 26.1)			
Fatigue: Moderate	14.8 (11.5 to 18.7)			
Fatigue: Severe	0.2 (0.0 to 1.4)			
Fatigue: Grade 4	0 (0.0 to 0.9)			
Headache: Any	35.3 (30.7 to 40.2)			
Headache: Mild	23.0 (19.0 to 27.4)			
Headache: Moderate	11.6 (8.7 to 15.1)			
Headache: Severe	0.7 (0.2 to 2.1)			
Headache: Grade 4	0 (0.0 to 0.9)			
Chills: Any	12.8 (9.7 to 16.5)			
Chills: Mild	8.4 (5.9 to 11.5)			
Chills: Moderate	4.4 (2.7 to 6.9)			
Chills: Severe	0 (0.0 to 0.9)			
Chills: Grade 4	0 (0.0 to 0.9)			
Vomiting: Any	2.7 (1.4 to 4.8)			
Vomiting: Mild	2.2 (1.0 to 4.2)			

Vomiting: Moderate	0.5 (0.1 to 1.8)			
Vomiting: Severe	0 (0.0 to 0.9)			
Vomiting: Grade 4	0 (0.0 to 0.9)			
Diarrhea: Any	4.4 (2.7 to 6.9)			
Diarrhea: Mild	4.0 (2.3 to 6.3)			
Diarrhea: Moderate	0.5 (0.1 to 1.8)			
Diarrhea: Severe	0 (0.0 to 0.9)			
Diarrhea: Grade 4	0 (0.0 to 0.9)			
New or worsened muscle pain: Any	18.8 (15.1 to 22.9)			
New or worsened muscle pain: Mild	10.6 (7.8 to 14.0)			
New or worsened muscle pain: Moderate	8.1 (5.7 to 11.3)			
New or worsened muscle pain: Severe	0 (0.0 to 0.9)			
New or worsened muscle pain: Grade 4	0 (0.0 to 0.9)			
New or worsened joint pain: Any	6.4 (4.2 to 9.3)			
New or worsened joint pain: Mild	4.0 (2.3 to 6.3)			
New or worsened joint pain: Moderate	2.5 (1.2 to 4.5)			
New or worsened joint pain: Severe	0 (0.0 to 0.9)			
New or worsened joint pain: Grade 4	0 (0.0 to 0.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: Troponin Group: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: Troponin Group: >=5 to <12 Years of age[45]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 1 to 1 month after dose 2 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 1 to 1 month after Dose 2

Notes:

[45] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years	Phase 2/3:Troponin group:Placebo:5 to <12 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	518	260		
Units: Percentage of participants				
number (confidence interval 95%)	7.1 (5.1 to 9.7)	8.1 (5.1 to 12.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: Troponin Group: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: Troponin Group: >=5 to <12 Years of age[46]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 3 to 1 month after dose 3 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 3 to 1 month after Dose 3

Notes:

[46] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years	Phase 2/3:Troponin group:Placebo:5 to <12 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	418	202		
Units: Percentage of participants				
number (confidence interval 95%)	11.5 (8.6 to 14.9)	15.3 (10.7 to 21.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: Troponin Group: >=12 to <16 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: Troponin Group: >=12 to <16 Years of age[47]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 1 to 1 month after dose 2 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 1 to 1 month after Dose 2

Notes:

[47] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162 b2 (30 mcg):12 to <16 years			
Subject group type	Reporting group			
Number of subjects analysed	487			
Units: Percentage of participants				
number (confidence interval 95%)	5.3 (3.5 to 7.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: Troponin Group:>=12 to <16 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: Troponin Group:>=12 to <16 Years of age[48]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 3 to 1 month after dose 3 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 3 to 1 month after Dose 3

Notes:

[48] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162b2 (30 mcg):12 to <16 years			
Subject group type	Reporting group			
Number of subjects analysed	433			
Units: Percentage of participants				
number (confidence interval 95%)	1.4 (0.5 to 3.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=5 to <12 Years of age[49]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)& G4 (necrosis[redness and swelling]or exfoliative dermatitis[redness]).Pain at injection site was graded as mild(did not interfere with activity),moderate (interfered with activity),severe (prevented daily activity)&G4 ER visit or hospitalisation for severe pain at injection site).G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included.Two-sided 95% CI was based on Clopper and Pearson method.Safety population=all participants who received at least 1 dose of study intervention.'N' signifies participants evaluable for this endpoint and 'n' signifies participants evaluable for the specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[49] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 2/3: Placebo: 5 to <12 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3096	1532		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any (3096,1532)	14.0 (12.8 to 15.3)	5.9 (4.8 to 7.2)		
Redness: Mild (3096,1532)	9.3 (8.3 to 10.3)	5.1 (4.0 to 6.3)		
Redness: Moderate (3096,1532)	4.7 (4.0 to 5.5)	0.7 (0.4 to 1.3)		
Redness: Severe (3096,1532)	0.0 (0.0 to 0.2)	0.1 (0.0 to 0.5)		
Redness: Grade 4 (3096,1532)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
Swelling: Any (3096,1532)	10.3 (9.3 to 11.5)	3.0 (2.2 to 4.0)		
Swelling: Mild (3096,1532)	5.7 (4.9 to 6.6)	1.8 (1.2 to 2.6)		

Swelling: Moderate (3096,1532)	4.6 (3.9 to 5.4)	1.2 (0.7 to 1.9)		
Swelling: Severe (3096,1532)	0.0 (0.0 to 0.2)	0 (0.0 to 0.2)		
Swelling: Grade 4 (3096,1532)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
Pain at the injection site: Any (3096,1531)	72.9 (71.3 to 74.5)	31.5 (29.2 to 33.9)		
Pain at the injection site: Mild (3096,1531)	58.5 (56.7 to 60.2)	28.3 (26.1 to 30.7)		
Pain at the injection site: Moderate (3096,1531)	14.3 (13.1 to 15.6)	3.1 (2.3 to 4.1)		
Pain at the injection site: Severe (3096,1531)	0.2 (0.1 to 0.4)	0 (0.0 to 0.2)		
Pain at the injection site: Grade 4 (3096,1531)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3 : Troponin Group:>=12 to <16 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3 : Troponin Group:>=12 to <16 Years of age[50]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 3 to 6 months after Dose 3

Notes:

[50] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162b2 (30 mcg):12 to <16 years			
Subject group type	Reporting group			
Number of subjects analysed	433			
Units: Percentage of participants				
number (confidence interval 95%)	1.4 (0.5 to 3.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: Troponin Group: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: Troponin Group: >=5 to <12 Years of age[51]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 3 to 6 months after Dose 3 (Approximately 6 months)

Notes:

[51] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years	Phase 2/3:Troponin group:Placebo:5 to <12 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	418	202		
Units: Percentage of participants				
number (confidence interval 95%)	0.5 (0.1 to 1.7)	0 (0.0 to 1.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2 : Troponin Group: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2 : Troponin Group: >=5 to <12 Years of age[52]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 1 to 6 months after Dose 2

Notes:

[52] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162 b2 (10 mcg):5 to <12 years	Phase 2/3:Troponin group:Placebo: 5 to <12 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	518	260		
Units: Percentage of participants				
number (confidence interval 95%)	0.2 (0.0 to 1.1)	0 (0.0 to 1.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: Troponin Group: >=12 to <16 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: Troponin Group: >=12 to <16 Years of age[53]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 1 to 6 months after Dose 2

Notes:

[53] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3:Troponin group:BNT162 b2 (30 mcg):12 to <16 years			
Subject group type	Reporting group			
Number of subjects analysed	487			
Units: Percentage of participants				
number (confidence interval 95%)	0.4 (0.0 to 1.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=5 to <12 Years of age[54]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)& G4 (necrosis[redness and swelling]or exfoliative dermatitis[redness]).Pain at injection site was graded as mild(did not interfere with activity),moderate (interfered with activity),severe (prevented daily activity)&G4 ER visit or hospitalisation for severe pain at injection site).G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included.Two-sided 95% CI was based on Clopper and Pearson method.Safety population=all participants who received at least 1 dose of study intervention.'N' signifies participants evaluable for this endpoint and 'n' signifies participants evaluable for the specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[54] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 2/3: Placebo: 5 to <12 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3064	1522		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any (3064, 1522)	18.8 (17.4 to 20.2)	5.2 (4.1 to 6.4)		
Redness: Mild (3064, 1522)	10.3 (9.2 to 11.4)	3.7 (2.8 to 4.8)		
Redness: Moderate (3064, 1522)	8.4 (7.4 to 9.4)	1.3 (0.8 to 2.0)		
Redness: Severe (3064, 1522)	0.1 (0.0 to 0.3)	0.1 (0.0 to 0.5)		
Redness: Grade 4 (3064, 1522)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
Swelling: Any (3064, 1522)	14.7 (13.5 to 16.0)	2.7 (1.9 to 3.6)		
Swelling: Mild (3064, 1522)	8.1 (7.1 to 9.1)	2.0 (1.3 to 2.8)		
Swelling: Moderate (3064, 1522)	6.6 (5.8 to 7.6)	0.7 (0.4 to 1.3)		
Swelling: Severe (3064, 1522)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
Swelling: Grade 4 (3064, 1522)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
Pain at the injection site: Any (3064, 1521)	71.2 (69.5 to 72.8)	28.5 (26.3 to 30.9)		
Pain at the injection site: Mild (3064, 1521)	53.6 (51.8 to 55.4)	25.6 (23.4 to 27.8)		
Pain at the injection site: Moderate (3064, 1521)	17.4 (16.1 to 18.8)	2.9 (2.1 to 3.9)		
Pain at the injection site: Severe (3064, 1521)	0.2 (0.1 to 0.4)	0.1 (0.0 to 0.4)		
Pain at the injection site: Grade 4 (3064, 1521)	0 (0.0 to 0.1)	0 (0.0 to 0.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=5 to <12 Years of age[55]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)& G4 (necrosis[redness and swelling]or exfoliative dermatitis[redness]).Pain at injection site was graded as mild(did not interfere with activity),moderate (interfered with activity),severe (prevented daily activity)&G4 ER visit or hospitalisation for severe pain at injection site).G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included.Two-sided 95% CI was based on Clopper and Pearson method.Safety population=all participants who received at least 1 dose of study intervention.'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[55] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age			
Subject group type	Reporting group			
Number of subjects analysed	2265			
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	15.6 (14.2 to 17.2)			
Redness: Mild	9.4 (8.3 to 10.7)			
Redness: Moderate	6.1 (5.1 to 7.2)			
Redness: Severe	0.1 (0.0 to 0.3)			
Redness: Grade 4	0 (0.0 to 0.2)			
Swelling: Any	12.6 (11.3 to 14.1)			
Swelling: Mild	6.5 (5.6 to 7.6)			
Swelling: Moderate	6.1 (5.1 to 7.2)			
Swelling: Severe	0 (0.0 to 0.2)			
Swelling: Grade 4	0 (0.0 to 0.2)			
Pain at the injection site: Any	69.2 (67.3 to 71.1)			
Pain at the injection site: Mild	48.0 (46.0 to 50.1)			
Pain at the injection site: Moderate	20.9 (19.3 to 22.7)			
Pain at the injection site: Severe	0.3 (0.1 to 0.6)			
Pain at the injection site: Grade 4	0 (0.0 to 0.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=5 to <12 Years of age[56]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments upto Day 7 after Dose 1. Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain &joint pain: mild(did not interfere with activity),moderate(some interference with activity),severe(prevented daily routine activity).Vomiting:mild:1-2 times in 24 h,moderate:>2 times in 24 h, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24h,moderate:4-5 loose stools in 24h,severe:6 or more loose stools in 24h.G4 for all events: ER visit/hospitalisation & were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95%CI based on Clopper and Pearson method. Safety population was used. 'N= participants evaluable for this endpoint & 'n'= participants evaluable for specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[56] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 2/3: Placebo: 5 to <12 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3096	1532		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever:>=38.0 (n=3096, 1532)	2.1 (1.6 to 2.6)	1.4 (0.9 to 2.1)		
Fever: 38.0 to 38.4 deg C (n=3096, 1532)	1.2 (0.8 to 1.6)	0.7 (0.3 to 1.2)		
Fever: >38.4 to 38.9 deg C (n=3096, 1532)	0.7 (0.4 to 1.1)	0.6 (0.3 to 1.1)		
Fever: >38.9 to 40.0 deg C (n=3096, 1532)	0.1 (0.0 to 0.3)	0.1 (0.0 to 0.5)		
Fever: >40.0 deg C (n=3096, 1532)	0.0 (0.0 to 0.2)	0 (0.0 to 0.2)		
Fatigue: Any (n=3096, 1531)	34.5 (32.8 to 36.2)	32.4 (30.1 to 34.8)		
Fatigue: Mild (n=3096, 1531)	22.7 (21.2 to 24.2)	21.1 (19.1 to 23.2)		
Fatigue: Moderate (n=3096, 1531)	11.6 (10.5 to 12.8)	11.2 (9.6 to 12.9)		
Fatigue: Severe (n=3096, 1531)	0.2 (0.1 to 0.4)	0.1 (0.0 to 0.5)		
Fatigue: Grade 4 (n=3096, 1531)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
Headache: Any (n=3096, 1531)	22.7 (21.2 to 24.2)	24.3 (22.2 to 26.5)		
Headache: Mild (n=3096, 1531)	17.1 (15.8 to 18.5)	18.0 (16.1 to 20.0)		
Headache: Moderate (n=3096, 1531)	5.5 (4.7 to 6.4)	5.9 (4.8 to 7.2)		
Headache: Severe (n=3096, 1531)	0.1 (0.0 to 0.3)	0.4 (0.1 to 0.9)		
Headache: Grade 4 (n=3096, 1531)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
Chills: Any (n=3096, 1531)	5.6 (4.8 to 6.5)	5.5 (4.4 to 6.7)		

Chills: Mild (n=3096, 1531)	4.5 (3.8 to 5.2)	4.5 (3.5 to 5.7)		
Chills: Moderate (n=3096, 1531)	1.2 (0.8 to 1.6)	1.0 (0.5 to 1.6)		
Chills: Severe (n=3096, 1531)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
Chills: Grade 4 (n=3096, 1531)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
Vomiting: Any (n=3096, 1531)	2.0 (1.6 to 2.6)	2.0 (1.3 to 2.8)		
Vomiting: Mild (n=3096, 1531)	1.7 (1.3 to 2.2)	1.8 (1.2 to 2.6)		
Vomiting: Moderate (n=3096, 1531)	0.4 (0.2 to 0.6)	0.1 (0.0 to 0.5)		
Vomiting: Severe (n=3096, 1531)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
Vomiting: Grade 4 (n=3096, 1531)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
Diarrhea: Any (n=3096, 1531)	6.4 (5.6 to 7.3)	4.9 (3.9 to 6.1)		
Diarrhea: Mild (n=3096, 1531)	5.9 (5.1 to 6.8)	4.7 (3.7 to 5.9)		
Diarrhea: Moderate (n=3096, 1531)	0.5 (0.2 to 0.8)	0.2 (0.0 to 0.6)		
Diarrhea: Severe (n=3096, 1531)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
Diarrhea: Grade 4 (n=3096, 1531)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
New or worsened muscle pain: Any(n=3096,1531)	9.3 (8.3 to 10.4)	8.2 (6.9 to 9.7)		
New or worsened muscle pain: Mild(n=3096,1531)	6.7 (5.8 to 7.6)	6.3 (5.1 to 7.6)		
New or worsened muscle pain: Moderate(n=3096,1531)	2.6 (2.1 to 3.3)	2.0 (1.3 to 2.8)		
New or worsened muscle pain: Severe(n=3096,1531)	0.0 (0.0 to 0.2)	0 (0.0 to 0.2)		
New or worsened muscle pain:G4 (n=3096,1531)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
New or worsened joint pain:Any (n=3096,1531)	3.4 (2.8 to 4.1)	4.6 (3.6 to 5.7)		
New or worsened joint pain:Mild (n=3096,1531)	2.3 (1.8 to 2.9)	3.7 (2.8 to 4.7)		
New or worsened joint pain:Moderate(n=3096,1531)	1.1 (0.8 to 1.6)	0.9 (0.5 to 1.5)		
New or worsened joint pain:Severe (n=3096,1531)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
New or worsened joint pain: G4 (n=3096,1531)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=5 to <12 Years of age[57]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments upto Day 7 after Dose 2. Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain &joint pain: mild(did not interfere with activity),moderate(some interference with activity),severe(prevented daily routine activity).Vomiting:mild:1-2 times in 24 h,moderate:>2 times in 24 h, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24h,moderate:4-5 loose stools in 24h,severe:6 or more loose stools in 24h.G4 for all events: ER visit/hospitalisation & were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95%CI based on Clopper and Pearson method. Safety population was used. 'N= participants evaluable for this endpoint & 'n'= participants evaluable for specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[57] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 2/3: Placebo: 5 to <12 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3064	1522		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: Any (n=3064, 1522)	6.3 (5.5 to 7.2)	1.4 (0.9 to 2.1)		
Fever: >=38.0 to 38.4 deg C (n=3064, 1522)	3.3 (2.7 to 4.0)	0.9 (0.5 to 1.5)		
Fever: >38.4 to 38.9 deg C (n=3064, 1522)	2.3 (1.8 to 2.9)	0.3 (0.1 to 0.8)		
Fever: >38.9 to 40.0 deg C (n=3064,1522)	0.7 (0.4 to 1.0)	0.2 (0.0 to 0.6)		
Fever: >40.0 deg C (n=3064, 1522)	0.0 (0.0 to 0.2)	0 (0.0 to 0.2)		
Fatigue: Any (n=3064, 1521)	39.2 (37.4 to 40.9)	25.2 (23.0 to 27.4)		
Fatigue: Mild (n=3064, 1521)	21.7 (20.3 to 23.2)	15.1 (13.4 to 17.0)		
Fatigue: Moderate (n=3064, 1521)	16.6 (15.3 to 17.9)	9.8 (8.3 to 11.4)		
Fatigue: Severe (n=3064, 1521)	0.9 (0.6 to 1.3)	0.3 (0.1 to 0.7)		
Fatigue: Grade 4 (n=3064, 1521)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
Headache: Any (n=3064, 1521)	28.4 (26.8 to 30.0)	18.7 (16.7 to 20.7)		
Headache: Mild (n=3064, 1521)	18.8 (17.4 to 20.2)	13.2 (11.6 to 15.0)		
Headache: Moderate (n=3064, 1521)	9.3 (8.3 to 10.4)	5.4 (4.3 to 6.6)		
Headache: Severe (n=3064, 1521)	0.3 (0.1 to 0.5)	0.1 (0.0 to 0.4)		
Headache: Grade 4 (n=3064, 1521)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
Chills: Any (n=3064, 1521)	9.8 (8.8 to 10.9)	4.3 (3.4 to 5.5)		
Chills: Mild (n=3064, 1521)	6.7 (5.8 to 7.6)	3.4 (2.6 to 4.5)		
Chills: Moderate (n=3064, 1521)	3.1 (2.5 to 3.7)	0.9 (0.5 to 1.5)		
Chills: Severe (n=3064, 1521)	0.1 (0.0 to 0.2)	0.1 (0.0 to 0.4)		
Chills: Grade 4 (n=3064, 1521)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
Vomiting: Any (n=3064, 1521)	2.0 (1.6 to 2.6)	1.8 (1.2 to 2.6)		
Vomiting: Mild (n=3064, 1521)	1.8 (1.4 to 2.4)	1.4 (0.9 to 2.2)		
Vomiting: Moderate (n=3064, 1521)	0.2 (0.1 to 0.4)	0.3 (0.1 to 0.8)		
Vomiting: Severe (n=3064, 1521)	0.0 (0.0 to 0.2)	0 (0.0 to 0.2)		
Vomiting: Grade 4 (n=3064, 1521)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
Diarrhea: Any (n=3064, 1521)	5.4 (4.6 to 6.3)	5.0 (4.0 to 6.2)		
Diarrhea: Mild (n=3064, 1521)	4.9 (4.1 to 5.7)	4.6 (3.6 to 5.8)		
Diarrhea: Moderate (n=3064, 1521)	0.5 (0.3 to 0.8)	0.4 (0.1 to 0.9)		
Diarrhea: Severe (n=3064, 1521)	0.1 (0.0 to 0.2)	0 (0.0 to 0.2)		
Diarrhea: Grade 4 (n=3064, 1521)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
New or worsened muscle pain:Any (n=3064,1521)	12.0 (10.9 to 13.2)	6.8 (5.6 to 8.2)		

New or worsened muscle pain:Mild (n=3064,1521)	8.0 (7.1 to 9.0)	4.5 (3.5 to 5.6)		
New or worsened muscle pain: Moderate(n=3064,1521)	4.0 (3.3 to 4.7)	2.4 (1.7 to 3.3)		
New or worsened muscle pain: Severe(n=3064,1521)	0.0 (0.0 to 0.2)	0 (0.0 to 0.2)		
New or worsened muscle pain:G4 (n=3064,1521)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
New or worsened joint pain:Any (n=3064,1521)	5.2 (4.4 to 6.0)	3.7 (2.9 to 4.8)		
New or worsened joint pain:Mild (n=3064,1521)	3.4 (2.8 to 4.1)	2.8 (2.0 to 3.7)		
New or worsened joint pain: Moderate(n=3064,1521)	1.8 (1.4 to 2.4)	1.0 (0.6 to 1.6)		
New or worsened joint pain: Severe (n=3064,1521)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		
New or worsened joint pain:G4 (n=3064,1521)	0 (0.0 to 0.1)	0 (0.0 to 0.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=5 to <12 Years of age[58]

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments upto Day 7 after Dose 3. Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain &joint pain: mild(did not interfere with activity),moderate(some interference with activity),severe(prevented daily routine activity).Vomiting:mild:1-2 times in 24 h,moderate:>2 times in 24 h, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24h,moderate:4-5 loose stools in 24h,severe:6 or more loose stools in 24h.G4 for all events: ER visit/hospitalisation & were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95%CI based on Clopper and Pearson method. Safety population was used. 'N= participants evaluable for this endpoint & 'n'= participants evaluable for specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[58] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age			
Subject group type	Reporting group			
Number of subjects analysed	2265			
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0	6.8 (5.8 to 7.9)			
Fever:38.0 to 38.4 deg C	4.1 (3.3 to 5.0)			

Fever: >38.4 to 38.9 deg C	1.8 (1.3 to 2.4)			
Fever: >38.9 to 40.0 deg C	0.9 (0.5 to 1.4)			
Fever: >40.0 deg C	0.0 (0.0 to 0.2)			
Fatigue: Any	39.6 (37.6 to 41.7)			
Fatigue: Mild	21.0 (19.4 to 22.8)			
Fatigue: Moderate	17.3 (15.8 to 18.9)			
Fatigue: Severe	1.3 (0.9 to 1.8)			
Fatigue: Grade 4	0 (0.0 to 0.2)			
Headache: Any	26.9 (25.1 to 28.8)			
Headache: Mild	16.2 (14.7 to 17.8)			
Headache: Moderate	10.3 (9.1 to 11.7)			
Headache: Severe	0.4 (0.2 to 0.8)			
Headache: Grade 4	0 (0.0 to 0.2)			
Chills: Any	10.2 (9.0 to 11.5)			
Chills: Mild	6.2 (5.2 to 7.3)			
Chills: Moderate	3.9 (3.1 to 4.8)			
Chills: Severe	0.1 (0.0 to 0.4)			
Chills: Grade 4	0 (0.0 to 0.2)			
Vomiting: Any	2.7 (2.1 to 3.4)			
Vomiting: Mild	2.2 (1.6 to 2.9)			
Vomiting: Moderate	0.4 (0.2 to 0.8)			
Vomiting: Severe	0.0 (0.0 to 0.2)			
Vomiting: Grade 4	0 (0.0 to 0.2)			
Diarrhea: Any	4.6 (3.8 to 5.5)			
Diarrhea: Mild	4.3 (3.5 to 5.2)			
Diarrhea: Moderate	0.3 (0.1 to 0.6)			
Diarrhea: Severe	0.0 (0.0 to 0.2)			
Diarrhea: Grade 4	0 (0.0 to 0.2)			
New or worsened muscle pain: Any	15.5 (14.0 to 17.0)			
New or worsened muscle pain: Mild	8.8 (7.7 to 10.0)			
New or worsened muscle pain: Moderate	6.5 (5.6 to 7.6)			
New or worsened muscle pain: Severe	0.1 (0.0 to 0.4)			
New or worsened muscle pain: Grade 4	0 (0.0 to 0.2)			
New or worsened joint pain: Any	5.7 (4.8 to 6.7)			
New or worsened joint pain: Mild	3.5 (2.8 to 4.3)			
New or worsened joint pain: Moderate	2.2 (1.6 to 2.9)			
New or worsened joint pain: Severe	0.0 (0.0 to 0.2)			
New or worsened joint pain: Grade 4	0 (0.0 to 0.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=2 to <5 Years of age

End point title	Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=2 to <5 Years of age[59]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)& G4 (necrosis[redness and swelling]or exfoliative dermatitis[redness]).Pain at injection site was graded as mild(did not interfere with activity),moderate (interfered with activity),severe (prevented daily activity)&G4 ER visit or hospitalisation.G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included.Two-sided 95% CI was based on Clopper and Pearson method.Safety population=all participants who received at least 1 dose of study intervention.'N' signifies participants evaluable for this endpoint and 'n' signifies participants evaluable for the specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[59] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 2/3: Placebo: 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2327	1164		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any (2327, 1164)	9.0 (7.9 to 10.3)	8.4 (6.9 to 10.2)		
Redness: Mild (2327, 1164)	7.7 (6.7 to 8.9)	7.5 (6.0 to 9.1)		
Redness: Moderate (2327, 1164)	1.2 (0.8 to 1.8)	0.9 (0.4 to 1.6)		
Redness: Severe (2327, 1164)	0.0 (0.0 to 0.2)	0.1 (0.0 to 0.5)		
Redness: Grade 4 (2327, 1164)	0 (0.0 to 0.2)	0 (0.0 to 0.3)		
Swelling: Any (2327, 1164)	3.9 (3.2 to 4.8)	3.1 (2.2 to 4.3)		
Swelling: Mild (2327, 1164)	3.4 (2.7 to 4.3)	2.5 (1.7 to 3.6)		
Swelling: Moderate (2327, 1164)	0.5 (0.2 to 0.8)	0.6 (0.2 to 1.2)		
Swelling: Severe (2327, 1164)	0 (0.0 to 0.2)	0 (0.0 to 0.3)		
Swelling: Grade 4 (2327, 1164)	0 (0.0 to 0.2)	0 (0.0 to 0.3)		
Pain at the injection site: Any (2305, 1159)	30.3 (28.4 to 32.2)	20.6 (18.3 to 23.1)		
Pain at the injection site: Mild (2305, 1159)	28.1 (26.3 to 30.0)	19.4 (17.2 to 21.8)		
Pain at the injection site: Moderate (2305, 1159)	2.2 (1.6 to 2.8)	1.1 (0.6 to 1.9)		
Pain at the injection site: Severe (2305, 1159)	0 (0.0 to 0.2)	0.1 (0.0 to 0.5)		
Pain at the injection site: Grade 4 (2305, 1159)	0 (0.0 to 0.2)	0 (0.0 to 0.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=2 to <5 Years of age

End point title	Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=2 to <5 Years of age[60]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)& G4 (necrosis[redness and swelling]or exfoliative dermatitis[redness]).Pain at injection site was graded as mild(did not interfere with activity),moderate (interfered with activity),severe (prevented daily activity)&G4 ER visit or hospitalisation.G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included.Two-sided 95% CI was based on Clopper and Pearson method.Safety population=all participants who received at least 1 dose of study intervention.'N' signifies participants evaluable for this endpoint and 'n' signifies participants evaluable for the specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[60] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 2/3: Placebo: 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2094	1038		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any (2094, 1038)	11.2 (9.9 to 12.7)	5.4 (4.1 to 6.9)		
Redness: Mild (2094, 1038)	9.6 (8.3 to 10.9)	4.6 (3.4 to 6.1)		
Redness: Moderate (2094, 1038)	1.6 (1.1 to 2.3)	0.8 (0.3 to 1.5)		
Redness: Severe (2094, 1038)	0.0 (0.0 to 0.3)	0 (0.0 to 0.4)		
Redness: Grade 4 (2094, 1038)	0.0 (0.0 to 0.2)	0 (0.0 to 0.4)		
Swelling: Any (2094, 1038)	5.6 (4.7 to 6.7)	2.0 (1.3 to 3.1)		
Swelling: Mild (2094, 1038)	4.4 (3.6 to 5.4)	1.8 (1.1 to 2.8)		
Swelling: Moderate (2094, 1038)	1.2 (0.8 to 1.8)	0.2 (0.0 to 0.7)		
Swelling: Severe (2094, 1038)	0 (0.0 to 0.2)	0 (0.0 to 0.4)		
Swelling: Grade 4 (2094, 1038)	0 (0.0 to 0.2)	0 (0.0 to 0.4)		
Pain at the injection site: Any (2082, 1037)	30.5 (28.5 to 32.5)	20.3 (17.9 to 22.9)		
Pain at the injection site: Mild (2082, 1037)	28.2 (26.3 to 30.2)	19.4 (17.0 to 21.9)		
Pain at the injection site: Moderate (2082, 1037)	2.2 (1.6 to 2.9)	0.9 (0.4 to 1.6)		
Pain at the injection site: Severe (2082, 1037)	0 (0.0 to 0.2)	0.1 (0.0 to 0.5)		
Pain at the injection site: Grade 4 (2082, 1037)	0 (0.0 to 0.2)	0 (0.0 to 0.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=2 to <5 Years of age

End point title	Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=2 to <5 Years of age[61]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)& G4 (necrosis[redness and swelling]or exfoliative dermatitis[redness]).Pain at injection site was graded as mild(did not interfere with activity),moderate (interfered with activity),severe (prevented daily activity)&G4 ER visit or hospitalisation.G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included.Two-sided 95% CI was based on Clopper and Pearson method.Safety population=all participants who received at least 1 dose of study intervention.'N' signifies participants evaluable for this endpoint and 'n' signifies participants evaluable for the specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[61] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 2/3: Placebo: 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	799	376		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any (799, 376)	10.4 (8.4 to 12.7)	4.8 (2.9 to 7.5)		
Redness: Mild (799, 376)	9.0 (7.1 to 11.2)	4.0 (2.2 to 6.5)		
Redness: Moderate (799, 376)	1.4 (0.7 to 2.4)	0.8 (0.2 to 2.3)		
Redness: Severe (799, 376)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		
Redness: Grade 4 (799, 376)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		
Swelling: Any (799, 376)	3.1 (2.0 to 4.6)	1.6 (0.6 to 3.4)		
Swelling: Mild (799, 376)	2.9 (1.8 to 4.3)	1.6 (0.6 to 3.4)		
Swelling: Moderate (799, 376)	0.3 (0.0 to 0.9)	0 (0.0 to 1.0)		
Swelling: Severe (799, 376)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		
Swelling: Grade 4 (799, 376)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		
Pain at the injection site: Any (793, 375)	28.0 (24.9 to 31.3)	12.8 (9.6 to 16.6)		
Pain at the injection site: Mild (793, 375)	26.0 (23.0 to 29.2)	12.0 (8.9 to 15.7)		

Pain at the injection site: Moderate (793, 375)	2.0 (1.2 to 3.3)	0.8 (0.2 to 2.3)		
Pain at the injection site: Severe (793, 375)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		
Pain at the injection site: Grade 4 (793, 375)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=2 to <5 Years of age

End point title	Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=2 to <5 Years of age[62]

End point description:

Systemic events were recorded in an e-diary & at unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Fever:oral temperature>= 38.0 deg C;categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C, >38.9 to 40.0 deg C & >40.0 deg C. Fatigue,headache,chills,new or worsened muscle pain and joint pain: mild(did not interfere with activity),moderate(some interference with activity),severe(prevented daily routine activity).Vomiting:mild: 1-2 times in 24 h,moderate:>2 times in 24 h, severe:required intravenous hydration.Diarrhea:mild:2-3 loose stools in 24 h,moderate:4-5 loose stools in 24 h,severe:6 or more loose stools in 24 h.G4 for all events: ER visit or hospitalisation& were classified by investigator or medically qualified person. Events reported as AEs in CRF within 7 days after vaccination were also included.Exact 95%CI based on Clopper and Pearson method. Safety population.N=participants evaluable for endpoint & n=participants evaluable for specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[62] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 2/3: Placebo: 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2325	1164		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever:>=38.0(n=2325, 1164)	5.5 (4.6 to 6.5)	5.7 (4.4 to 7.2)		
Fever: 38.0 to 38.4 deg C (n=2325, 1164)	3.1 (2.4 to 3.8)	2.6 (1.7 to 3.7)		
Fever: >38.4 to 38.9 deg C (n=2325, 1164)	1.5 (1.0 to 2.0)	2.1 (1.3 to 3.1)		
Fever: >38.9 to 40.0 deg C (n=2325, 1164)	0.9 (0.6 to 1.4)	1.0 (0.5 to 1.8)		
Fever: >40.0 deg C (n=2325, 1164)	0.1 (0.0 to 0.3)	0 (0.0 to 0.3)		
Fatigue: Any (n=2304, 1159)	30.6 (28.7 to 32.5)	31.9 (29.2 to 34.7)		
Fatigue: Mild (n=2304, 1159)	18.8 (17.2 to 20.4)	19.5 (17.3 to 21.9)		
Fatigue: Moderate (n=2304, 1159)	11.5 (10.2 to 12.8)	11.6 (9.9 to 13.6)		

Fatigue: Severe (n=2304, 1159)	0.4 (0.2 to 0.7)	0.8 (0.4 to 1.5)		
Fatigue: Grade 4 (n=2304, 1159)	0 (0.0 to 0.2)	0 (0.0 to 0.3)		
Headache: Any (n=2304, 1159)	5.1 (4.2 to 6.1)	4.8 (3.7 to 6.2)		
Headache: Mild (n=2304, 1159)	3.9 (3.2 to 4.8)	3.7 (2.7 to 5.0)		
Headache: Moderate (n=2304, 1159)	1.1 (0.7 to 1.6)	1.0 (0.5 to 1.8)		
Headache: Severe (n=2304, 1159)	0 (0.0 to 0.2)	0.1 (0.0 to 0.5)		
Headache: Grade 4 (n=2304, 1159)	0 (0.0 to 0.2)	0 (0.0 to 0.3)		
Chills: Any (n=2304, 1159)	2.8 (2.1 to 3.5)	2.9 (2.0 to 4.1)		
Chills: Mild (n=2304, 1159)	1.8 (1.3 to 2.4)	2.0 (1.3 to 3.0)		
Chills: Moderate (n=2304, 1159)	0.9 (0.5 to 1.3)	0.9 (0.4 to 1.6)		
Chills: Severe (n=2304, 1159)	0.1 (0.0 to 0.4)	0.1 (0.0 to 0.5)		
Chills: Grade 4 (n=2304, 1159)	0 (0.0 to 0.2)	0 (0.0 to 0.3)		
Vomiting: Any (n=2304, 1159)	3.5 (2.8 to 4.4)	2.9 (2.0 to 4.1)		
Vomiting: Mild (n=2304, 1159)	2.9 (2.2 to 3.6)	2.1 (1.3 to 3.1)		
Vomiting: Moderate (n=2304, 1159)	0.7 (0.4 to 1.1)	0.9 (0.4 to 1.6)		
Vomiting: Severe (n=2304, 1159)	0 (0.0 to 0.2)	0 (0.0 to 0.3)		
Vomiting: Grade 4 (n=2304, 1159)	0 (0.0 to 0.2)	0 (0.0 to 0.3)		
Diarrhea: Any (n=2304, 1159)	8.6 (7.4 to 9.8)	8.3 (6.8 to 10.0)		
Diarrhea: Mild (n=2304, 1159)	7.9 (6.8 to 9.0)	7.4 (6.0 to 9.1)		
Diarrhea: Moderate (n=2304, 1159)	0.7 (0.4 to 1.1)	0.9 (0.4 to 1.6)		
Diarrhea: Severe (n=2304, 1159)	0 (0.0 to 0.2)	0 (0.0 to 0.3)		
Diarrhea: Grade 4 (n=2304, 1159)	0 (0.0 to 0.2)	0 (0.0 to 0.3)		
New or worsened muscle pain:Any (n=2304,1159)	2.6 (2.0 to 3.3)	2.3 (1.5 to 3.4)		
New or worsened muscle pain: Mild (n=2304,1159)	1.9 (1.4 to 2.6)	1.7 (1.1 to 2.7)		
New or worsened muscle pain: Moderate(n=2304,1159)	0.7 (0.4 to 1.1)	0.5 (0.2 to 1.1)		
New or worsened muscle pain: Severe(n=2304,1159)	0.0 (0.0 to 0.2)	0.1 (0.0 to 0.5)		
New or worsened muscle pain: G4(n=2304,1159)	0 (0.0 to 0.2)	0 (0.0 to 0.3)		
New or worsened joint pain: Any (n=2304,1159)	1.2 (0.8 to 1.7)	1.8 (1.1 to 2.8)		
New or worsened joint pain:Mild (n=2304,1159)	0.9 (0.6 to 1.4)	1.4 (0.8 to 2.2)		
New or worsened joint pain: Moderate(n=2304,1159)	0.2 (0.1 to 0.5)	0.4 (0.1 to 1.0)		
New or worsened joint pain:Severe (n=2304,1159)	0.0 (0.0 to 0.2)	0 (0.0 to 0.3)		
New or worsened joint pain: G4 (n=2304,1159)	0 (0.0 to 0.2)	0 (0.0 to 0.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=2 to <5 Years of age

End point title	Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=2 to <5 Years of age[63]

End point description:

Systemic events were recorded in an e-diary & at unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Fever:oral temperature>= 38.0 deg C;categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C, >38.9 to 40.0 deg C & >40.0 deg C. Fatigue,headache,chills,new or worsened muscle pain and joint pain: mild(did not interfere with activity),moderate(some interference with activity),severe(prevented daily routine activity).Vomiting:mild: 1-2 times in 24 h,moderate:>2 times in 24 h, severe:required intravenous hydration.Diarrhea:mild:2-3 loose stools in 24 h,moderate:4-5 loose stools in 24 h,severe:6 or more loose stools in 24 h.G4 for all events: ER visit or hospitalisation& were classified by investigator or medically qualified person. Events reported as AEs in CRF within 7 days after vaccination were also included.Exact 95%CI based on Clopper and Pearson method. Safety population.N=participants evaluable for endpoint & n=participants evaluable for specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[63] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 2/3: Placebo: 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2094	1038		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 (n=2094, 1038)	5.2 (4.3 to 6.2)	5.8 (4.4 to 7.4)		
Fever:38.0 to 38.4 deg C (n=2094, 1038)	2.4 (1.8 to 3.2)	2.2 (1.4 to 3.3)		
Fever: >38.4 to 38.9 deg C (n=2094, 1038)	1.5 (1.0 to 2.2)	2.6 (1.7 to 3.8)		
Fever: >38.9 to 40.0 deg C (n=2094, 1038)	1.1 (0.7 to 1.6)	0.9 (0.4 to 1.6)		
Fever: >40.0 deg C (n=2094, 1038)	0.1 (0.0 to 0.4)	0.1 (0.0 to 0.5)		
Fatigue: Any (n=2082, 1037)	26.1 (24.2 to 28.0)	24.3 (21.7 to 27.0)		
Fatigue: Mild (n=2082, 1037)	15.5 (13.9 to 17.1)	14.7 (12.6 to 17.0)		
Fatigue: Moderate (n=2082, 1037)	10.2 (9.0 to 11.6)	9.3 (7.6 to 11.2)		
Fatigue: Severe (n=2082, 1037)	0.4 (0.2 to 0.8)	0.4 (0.1 to 1.0)		
Fatigue: Grade 4 (n=2082, 1037)	0 (0.0 to 0.2)	0 (0.0 to 0.4)		
Headache: Any (n=2082, 1037)	4.6 (3.8 to 5.6)	4.1 (3.0 to 5.5)		
Headache: Mild (n=2082, 1037)	3.5 (2.7 to 4.3)	2.6 (1.7 to 3.8)		
Headache: Moderate (n=2082, 1037)	1.2 (0.7 to 1.7)	1.4 (0.8 to 2.4)		
Headache: Severe (n=2082, 1037)	0 (0.0 to 0.2)	0.1 (0.0 to 0.5)		
Headache: Grade 4 (n=2082, 1037)	0 (0.0 to 0.2)	0 (0.0 to 0.4)		
Chills: Any (n=2082, 1037)	3.2 (2.5 to 4.0)	2.8 (1.9 to 4.0)		
Chills: Mild (n=2082, 1037)	2.2 (1.6 to 2.9)	2.2 (1.4 to 3.3)		
Chills: Moderate (n=2082, 1037)	1.0 (0.6 to 1.5)	0.6 (0.2 to 1.3)		
Chills: Severe (n=2082, 1037)	0 (0.0 to 0.2)	0 (0.0 to 0.4)		
Chills: Grade 4 (n=2082, 1037)	0 (0.0 to 0.2)	0 (0.0 to 0.4)		
Vomiting: Any (n=2082, 1037)	3.4 (2.6 to 4.2)	3.4 (2.4 to 4.7)		
Vomiting: Mild (n=2082, 1037)	3.0 (2.3 to 3.8)	2.9 (2.0 to 4.1)		
Vomiting: Moderate (n=2082, 1037)	0.4 (0.2 to 0.8)	0.5 (0.2 to 1.1)		
Vomiting: Severe (n=2082, 1037)	0 (0.0 to 0.2)	0 (0.0 to 0.4)		

Vomiting: Grade 4 (n=2082, 1037)	0 (0.0 to 0.2)	0 (0.0 to 0.4)		
Diarrhea: Any (n=2082, 1037)	6.8 (5.7 to 7.9)	8.0 (6.4 to 9.8)		
Diarrhea: Mild (n=2082, 1037)	5.9 (4.9 to 7.0)	7.1 (5.6 to 8.9)		
Diarrhea: Moderate (n=2082, 1037)	0.8 (0.5 to 1.3)	0.8 (0.3 to 1.5)		
Diarrhea: Severe (n=2082, 1037)	0.1 (0.0 to 0.3)	0.1 (0.0 to 0.5)		
Diarrhea: Grade 4 (n=2082, 1037)	0 (0.0 to 0.2)	0 (0.0 to 0.4)		
New or worsened muscle pain: Any (n=2082, 1037)	2.6 (2.0 to 3.4)	2.6 (1.7 to 3.8)		
New or worsened muscle pain:Mild (n=2082,1037)	1.9 (1.3 to 2.6)	2.0 (1.3 to 3.1)		
New or worsened muscle pain: Moderate(n=2082,1037)	0.8 (0.4 to 1.2)	0.6 (0.2 to 1.3)		
New or worsened muscle pain: Severe(n=2082,1037)	0 (0.0 to 0.2)	0 (0.0 to 0.4)		
New or worsened muscle pain: G4 (n=2082,1037)	0 (0.0 to 0.2)	0 (0.0 to 0.4)		
New or worsened joint pain:Any (n=2082,1037)	1.2 (0.8 to 1.8)	1.2 (0.6 to 2.0)		
New or worsened joint pain:Mild (n=2082,1037)	0.9 (0.6 to 1.4)	0.9 (0.4 to 1.6)		
New or worsened joint pain: Moderate(n=2082,1037)	0.3 (0.1 to 0.7)	0.3 (0.1 to 0.8)		
New or worsened joint pain:Severe (n=2082,1037)	0 (0.0 to 0.2)	0 (0.0 to 0.4)		
New or worsened joint pain:G4 (n=2082,1037)	0 (0.0 to 0.2)	0 (0.0 to 0.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=2 to <5 Years of age

End point title	Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=2 to <5 Years of age[64]

End point description:

Systemic events were recorded in an e-diary & at unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Fever:oral temperature>= 38.0 deg C;categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C, >38.9 to 40.0 deg C & >40.0 deg C. Fatigue,headache,chills,new or worsened muscle pain and joint pain: mild(did not interfere with activity),moderate(some interference with activity),severe(prevented daily routine activity).Vomiting:mild: 1-2 times in 24 h,moderate:>2 times in 24 h, severe:required intravenous hydration.Diarrhea:mild:2-3 loose stools in 24 h,moderate:4-5 loose stools in 24 h,severe:6 or more loose stools in 24 h.G4 for all events: ER visit or hospitalisation& were classified by investigator or medically qualified person. Events reported as AEs in CRF within 7 days after vaccination were also included.Exact 95%CI based on Clopper and Pearson method. Safety population.N=participants evaluable for endpoint & n=participants evaluable for specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[64] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 2/3: Placebo: 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	799	376		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 (n=799, 376)	5.1 (3.7 to 6.9)	5.6 (3.5 to 8.4)		
Fever:38.0 to 38.4 deg C (n=799, 376)	2.5 (1.5 to 3.8)	2.1 (0.9 to 4.1)		
Fever: >38.4 to 38.9 deg C (n=799, 376)	1.8 (1.0 to 2.9)	1.9 (0.8 to 3.8)		
Fever: >38.9 to 40.0 deg C (n=799, 376)	0.9 (0.4 to 1.8)	1.6 (0.6 to 3.4)		
Fever: >40.0 deg C (n=799, 376)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		
Fatigue: Any (n=793, 375)	25.5 (22.5 to 28.7)	24.3 (20.0 to 28.9)		
Fatigue: Mild (n=793, 375)	16.0 (13.5 to 18.8)	14.7 (11.2 to 18.7)		
Fatigue: Moderate (n=793, 375)	9.2 (7.3 to 11.4)	9.3 (6.6 to 12.7)		
Fatigue: Severe (n=793, 375)	0.3 (0.0 to 0.9)	0.3 (0.0 to 1.5)		
Fatigue: Grade 4 (n=793, 375)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		
Headache: Any (n=793, 375)	4.5 (3.2 to 6.2)	4.0 (2.3 to 6.5)		
Headache: Mild (n=793, 375)	2.9 (1.8 to 4.3)	2.9 (1.5 to 5.2)		
Headache: Moderate (n=793, 375)	1.6 (0.9 to 2.8)	1.1 (0.3 to 2.7)		
Headache: Severe (n=793, 375)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		
Headache: Grade 4 (n=793, 375)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		
Chills: Any (n=793, 375)	2.8 (1.7 to 4.2)	2.7 (1.3 to 4.8)		
Chills: Mild (n=793, 375)	2.1 (1.3 to 3.4)	2.4 (1.1 to 4.5)		
Chills: Moderate (n=793, 375)	0.5 (0.1 to 1.3)	0.3 (0.0 to 1.5)		
Chills: Severe (n=793, 375)	0.1 (0.0 to 0.7)	0 (0.0 to 1.0)		
Chills: Grade 4 (n=793, 375)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		
Vomiting: Any (n=793, 375)	2.0 (1.2 to 3.3)	4.3 (2.5 to 6.8)		
Vomiting: Mild (n=793, 375)	1.5 (0.8 to 2.6)	2.9 (1.5 to 5.2)		
Vomiting: Moderate (n=793, 375)	0.5 (0.1 to 1.3)	1.3 (0.4 to 3.1)		
Vomiting: Severe (n=793, 375)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		
Vomiting: Grade 4 (n=793, 375)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		
Diarrhea: Any (n=793, 375)	4.9 (3.5 to 6.7)	5.6 (3.5 to 8.4)		
Diarrhea: Mild (n=793, 375)	3.8 (2.6 to 5.4)	4.5 (2.7 to 7.2)		
Diarrhea: Moderate (n=793, 375)	1.1 (0.5 to 2.1)	1.1 (0.3 to 2.7)		
Diarrhea: Severe (n=793, 375)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		
Diarrhea: Grade 4 (n=793, 375)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		
New or worsened muscle pain: Any (n=793, 375)	1.9 (1.1 to 3.1)	1.6 (0.6 to 3.4)		
New or worsened muscle pain: Mild (n=793, 375)	1.5 (0.8 to 2.6)	1.3 (0.4 to 3.1)		
New or worsened muscle pain: Moderate (n=793, 375)	0.4 (0.1 to 1.1)	0.3 (0.0 to 1.5)		
New or worsened muscle pain: Severe (n=793, 375)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		
New or worsened muscle pain: Grade 4 (n=793, 375)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		
New or worsened joint pain: Any (n=793, 375)	1.1 (0.5 to 2.1)	1.1 (0.3 to 2.7)		

New or worsened joint pain: Mild (n=793, 375)	0.9 (0.4 to 1.8)	1.1 (0.3 to 2.7)		
New or worsened joint pain: Moderate (n=793, 375)	0.1 (0.0 to 0.7)	0 (0.0 to 1.0)		
New or worsened joint pain: Severe (n=793, 375)	0.1 (0.0 to 0.7)	0 (0.0 to 1.0)		
New or worsened joint pain: Grade 4 (n=793, 375)	0 (0.0 to 0.5)	0 (0.0 to 1.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=6 Months to <2 Years of age

End point title	Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=6 Months to <2 Years of age[65]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 1. Redness and swelling were measured and recorded in mdu where,1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm), moderate (>2.0 to 7.0 cm), severe (>7.0 cm) & G4 (necrosis [redness and swelling] or exfoliative dermatitis [redness]). Tenderness at injection site was graded as mild (hurts if gently touched), moderate(hurts if gently touched with crying), severe (causes limitation of limb movement) & G4 (ER visit or hospitalisation).G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population was used. 'N=participants evaluable for this endpoint and 'n=participants evaluable for the specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[65] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Phase 2/3: Placebo: 6 months to <2 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1439	712		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any (n=1439, 712)	10.7 (9.2 to 12.4)	7.6 (5.7 to 9.8)		
Redness: Mild (n=1439, 712)	9.8 (8.3 to 11.5)	7.2 (5.4 to 9.3)		
Redness: Moderate (n=1439, 712)	0.9 (0.5 to 1.5)	0.4 (0.1 to 1.2)		
Redness: Severe (n=1439, 712)	0 (0.0 to 0.3)	0 (0.0 to 0.5)		
Redness: Grade 4 (n=1439, 712)	0 (0.0 to 0.3)	0 (0.0 to 0.5)		
Swelling: Any (n=1439, 712)	3.8 (2.8 to 4.9)	2.5 (1.5 to 4.0)		
Swelling: Mild (n=1439, 712)	3.3 (2.5 to 4.4)	2.2 (1.3 to 3.6)		
Swelling: Moderate (n=1439, 712)	0.4 (0.2 to 0.9)	0.3 (0.0 to 1.0)		
Swelling: Severe (n=1439, 712)	0 (0.0 to 0.3)	0 (0.0 to 0.5)		

Swelling: Grade 4 (n=1439, 712)	0 (0.0 to 0.3)	0 (0.0 to 0.5)		
Tenderness at injection site: Any (n=1425, 706)	17.2 (15.3 to 19.3)	12.6 (10.2 to 15.3)		
Tenderness at injection site: Mild (n=1425, 706)	16.3 (14.4 to 18.3)	11.5 (9.2 to 14.1)		
Tenderness at injection site:Moderate (n=1425,706)	0.8 (0.4 to 1.5)	1.1 (0.5 to 2.2)		
Tenderness at injection site:Severe(n=1425,706)	0.1 (0.0 to 0.4)	0 (0.0 to 0.5)		
Tenderness at injection site: G4 (n=1425, 706)	0 (0.0 to 0.3)	0 (0.0 to 0.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=6 Months to <2 Years of age

End point title	Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=6 Months to <2 Years of age[66]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 2. Redness and swelling were measured and recorded in mdu where,1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm), moderate (>2.0 to 7.0 cm), severe (>7.0 cm) & G4 (necrosis [redness and swelling] or exfoliative dermatitis [redness]). Tenderness at injection site was graded as mild (hurts if gently touched), moderate(hurts if gently touched with crying), severe (causes limitation of limb movement) & G4 (ER visit or hospitalisation).G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population was used. 'N=participants evaluable for this endpoint and 'n=participants evaluable for the specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[66] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Phase 2/3: Placebo: 6 months to <2 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1323	666		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any (n= 1323,666)	9.9 (8.3 to 11.6)	6.3 (4.6 to 8.4)		
Redness: Mild (n= 1323,666)	9.1 (7.6 to 10.7)	5.9 (4.2 to 7.9)		
Redness: Moderate (n= 1323,666)	0.8 (0.4 to 1.5)	0.5 (0.1 to 1.3)		
Redness: Severe (n= 1323,666)	0 (0.0 to 0.3)	0 (0.0 to 0.6)		
Redness: Grade 4 (n= 1323,666)	0 (0.0 to 0.3)	0 (0.0 to 0.6)		
Swelling: Any (n= 1323,666)	4.1 (3.1 to 5.3)	1.5 (0.7 to 2.7)		

Swelling: Mild (n= 1323,666)	3.5 (2.6 to 4.6)	1.4 (0.6 to 2.5)		
Swelling: Moderate (n= 1323,666)	0.6 (0.3 to 1.2)	0.2 (0.0 to 0.8)		
Swelling: Severe (n= 1323,666)	0 (0.0 to 0.3)	0 (0.0 to 0.6)		
Swelling: Grade 4 (n= 1323,666)	0 (0.0 to 0.3)	0 (0.0 to 0.6)		
Tenderness at injection site: Any(n= 1314,664)	15.4 (13.5 to 17.5)	9.3 (7.2 to 11.8)		
Tenderness at injection site:Mild (n= 1314,664)	13.8 (12.0 to 15.8)	7.7 (5.8 to 10.0)		
Tenderness at injection site:Moderate(n=1314,664)	1.6 (1.0 to 2.4)	1.7 (0.8 to 2.9)		
Tenderness at injection site:Severe (n= 1314,664)	0.1 (0.0 to 0.4)	0 (0.0 to 0.6)		
Tenderness at injection site: G4 (n= 1314,664)	0 (0.0 to 0.3)	0 (0.0 to 0.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=6 Months to <2 Years of age

End point title	Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=6 Months to <2 Years of age[67]

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 3. Redness and swelling were measured and recorded in mdu where,1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm), moderate (>2.0 to 7.0 cm), severe (>7.0 cm) & G4 (necrosis [redness and swelling] or exfoliative dermatitis [redness]). Tenderness at injection site was graded as mild (hurts if gently touched), moderate(hurts if gently touched with crying), severe (causes limitation of limb movement) & G4 (ER visit or hospitalisation).G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population was used. 'N=participants evaluable for this endpoint and 'n=participants evaluable for the specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[67] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Phase 2/3: Placebo: 6 months to <2 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	459	222		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any (n=459,222)	7.2 (5.0 to 9.9)	5.0 (2.5 to 8.7)		
Redness: Mild (n=459,222)	5.0 (3.2 to 7.4)	4.5 (2.2 to 8.1)		
Redness: Moderate (n=459,222)	2.0 (0.9 to 3.7)	0.5 (0.0 to 2.5)		
Redness: Severe (n=459,222)	0.2 (0.0 to 1.2)	0 (0.0 to 1.6)		

Redness: Grade 4 (n=459,222)	0 (0.0 to 0.8)	0 (0.0 to 1.6)		
Swelling: Any (n=459,222)	3.3 (1.8 to 5.3)	2.3 (0.7 to 5.2)		
Swelling: Mild (n=459,222)	2.0 (0.9 to 3.7)	2.3 (0.7 to 5.2)		
Swelling: Moderate (n=459,222)	1.3 (0.5 to 2.8)	0 (0.0 to 1.6)		
Swelling: Severe (n=459,222)	0 (0.0 to 0.8)	0 (0.0 to 1.6)		
Swelling: Grade 4 (n=459,222)	0 (0.0 to 0.8)	0 (0.0 to 1.6)		
Tenderness at injection site:Any (n=455,222)	14.7 (11.6 to 18.3)	9.9 (6.3 to 14.6)		
Tenderness at injection site:Mild (n=455,222)	13.0 (10.0 to 16.4)	8.6 (5.2 to 13.0)		
Tenderness at injection site: Moderate(n=455,222)	1.8 (0.8 to 3.4)	1.4 (0.3 to 3.9)		
Tenderness at injection site:Severe (n=455,222)	0 (0.0 to 0.8)	0 (0.0 to 1.6)		
Tenderness at injection site: G4 (n=455,222)	0 (0.0 to 0.8)	0 (0.0 to 1.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=6 Months to <2 Years of age

End point title	Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=6 Months to <2 Years of age[68]

End point description:

Systemic events recorded in an e-diary & at unscheduled clinical assessments up to Day 7 after Dose 1. Fever: oral temperature >= 38.0 deg C; categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C, >38.9 to 40.0 deg C & >40.0 deg C. Decreased appetite: mild (decreased interest in eating),moderate(decreased oral intake),severe(refusal to feed). Drowsiness: mild(increased or prolonged sleeping bouts),moderate(slightly subdued interfering with daily activity),severe(disabling;not interested in usual daily activity).Irritability:mild(easily consolable),moderate(requiring increased attention),severe(Inconsolable; crying cannot be comforted).G4 for all events: ER visit or hospitalisation & were classified by investigator or medically qualified person. Events reported as AEs in CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. N=participants evaluable for this endpoint & n=participants evaluable for specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[68] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Phase 2/3: Placebo: 6 months to <2 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1439	712		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 (n=1439,712)	7.2 (5.9 to 8.7)	7.4 (5.6 to 9.6)		
Fever: 38.0 to 38.4 deg C (n=1439,712)	3.4 (2.5 to 4.5)	3.5 (2.3 to 5.1)		

Fever: >38.4 to 38.9 deg C (n=1439,712)	2.2 (1.5 to 3.1)	2.5 (1.5 to 4.0)		
Fever: >38.9 to 40.0 deg C (n=1439,712)	1.5 (1.0 to 2.3)	1.3 (0.6 to 2.4)		
Fever: >40.0 deg C (n=1439,712)	0.1 (0.0 to 0.4)	0.1 (0.0 to 0.8)		
Decreased appetite: Any (n=1425,706)	22.7 (20.5 to 24.9)	21.2 (18.3 to 24.5)		
Decreased appetite: Mild (n=1425,706)	12.4 (10.7 to 14.2)	12.0 (9.7 to 14.7)		
Decreased appetite: Moderate (n=1425,706)	10.1 (8.6 to 11.8)	8.9 (6.9 to 11.3)		
Decreased appetite: Severe (n=1425,706)	0.2 (0.0 to 0.6)	0.3 (0.0 to 1.0)		
Decreased appetite: Grade 4 (n=1425,706)	0 (0.0 to 0.3)	0 (0.0 to 0.5)		
Drowsiness: Any (n=1425,706)	27.8 (25.5 to 30.2)	30.0 (26.7 to 33.6)		
Drowsiness: Mild (n=1425,706)	22.0 (19.8 to 24.2)	22.7 (19.6 to 25.9)		
Drowsiness: Moderate (n=1425,706)	5.6 (4.5 to 6.9)	6.9 (5.2 to 9.1)		
Drowsiness: Severe (n=1425,706)	0.2 (0.0 to 0.6)	0.4 (0.1 to 1.2)		
Drowsiness: Grade 4 (n=1425,706)	0 (0.0 to 0.3)	0 (0.0 to 0.5)		
Irritability: Any (n=1425,706)	51.0 (48.4 to 53.6)	48.2 (44.4 to 51.9)		
Irritability: Mild (n=1425,706)	20.6 (18.6 to 22.8)	18.3 (15.5 to 21.3)		
Irritability: Moderate (n=1425,706)	29.7 (27.3 to 32.1)	29.6 (26.3 to 33.1)		
Irritability: Severe (n=1425,706)	0.7 (0.3 to 1.3)	0.3 (0.0 to 1.0)		
Irritability: Grade 4 (n=1425,706)	0 (0.0 to 0.3)	0 (0.0 to 0.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=6 Months to <2 Years of age

End point title	Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=6 Months to <2 Years of age[69]

End point description:

Systemic events recorded in an e-diary & at unscheduled clinical assessments up to Day 7 after Dose 2. Fever: oral temperature >= 38.0 deg C; categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C, >38.9 to 40.0 deg C & >40.0 deg C. Decreased appetite: mild (decreased interest in eating),moderate(decreased oral intake),severe(refusal to feed). Drowsiness: mild(increased or prolonged sleeping bouts),moderate(slightly subdued interfering with daily activity),severe(disabling;not interested in usual daily activity).Irritability:mild(easily consolable),moderate(requiring increased attention),severe(Inconsolable; crying cannot be comforted).G4 for all events: ER visit or hospitalisation & were classified by investigator or medically qualified person. Events reported as AEs in CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. N=participants evaluable for this endpoint & n=participants evaluable for specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[69] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Phase 2/3: Placebo: 6 months to <2 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1322	666		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 (n=1322,666)	7.6 (6.3 to 9.2)	6.5 (4.7 to 8.6)		
Fever: 38.0 to 38.4 deg C (n=1322,666)	3.6 (2.7 to 4.8)	3.6 (2.3 to 5.3)		
Fever: >38.4 to 38.9 deg C (n=1322,666)	2.0 (1.4 to 3.0)	1.7 (0.8 to 2.9)		
Fever: >38.9 to 40.0 deg C (n=1322,666)	1.9 (1.2 to 2.8)	1.2 (0.5 to 2.4)		
Fever: >40.0 deg C (n=1322,666)	0.1 (0.0 to 0.4)	0 (0.0 to 0.6)		
Decreased appetite: Any (n=1314,664)	22.5 (20.3 to 24.9)	19.4 (16.5 to 22.6)		
Decreased appetite: Mild (n=1314,664)	13.9 (12.1 to 15.9)	11.3 (9.0 to 14.0)		
Decreased appetite: Moderate (n=1314,664)	8.1 (6.7 to 9.8)	8.0 (6.0 to 10.3)		
Decreased appetite: Severe (n=1314,664)	0.5 (0.2 to 1.0)	0.2 (0.0 to 0.8)		
Decreased appetite: Grade 4 (n=1314,664)	0 (0.0 to 0.3)	0 (0.0 to 0.6)		
Drowsiness: Any (n=1314,664)	24.1 (21.8 to 26.5)	21.4 (18.3 to 24.7)		
Drowsiness: Mild (n=1314,664)	17.8 (15.8 to 20.0)	16.9 (14.1 to 19.9)		
Drowsiness: Moderate (n=1314,664)	6.0 (4.8 to 7.4)	4.4 (2.9 to 6.2)		
Drowsiness: Severe (n=1314,664)	0.3 (0.1 to 0.8)	0.2 (0.0 to 0.8)		
Drowsiness: Grade 4 (n=1314,664)	0 (0.0 to 0.3)	0 (0.0 to 0.6)		
Irritability: Any (n=1314,664)	46.9 (44.2 to 49.6)	41.4 (37.6 to 45.3)		
Irritability: Mild (n=1314,664)	18.5 (16.4 to 20.7)	15.8 (13.1 to 18.8)		
Irritability: Moderate (n=1314,664)	27.8 (25.4 to 30.3)	24.7 (21.5 to 28.2)		
Irritability: Severe (n=1314,664)	0.6 (0.3 to 1.2)	0.9 (0.3 to 2.0)		
Irritability: Grade 4 (n=1314,664)	0 (0.0 to 0.3)	0 (0.0 to 0.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=6 Months to <2 Years of age

End point title	Phase 2/3: Percentage of Participants With Systemic Events

	Within 7 Days After Dose 3: >=6 Months to <2 Years of age[70]

End point description:

Systemic events recorded in an e-diary & at unscheduled clinical assessments up to Day 7 after Dose 3. Fever: oral temperature >= 38.0 deg C; categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C, >38.9 to 40.0 deg C & >40.0 deg C. Decreased appetite: mild (decreased interest in eating),moderate(decreased oral intake),severe(refusal to feed). Drowsiness: mild(increased or prolonged sleeping bouts),moderate(slightly subdued interfering with daily activity),severe(disabling;not interested in usual daily activity).Irritability:mild(easily consolable),moderate(requiring increased attention),severe(Inconsolable; crying cannot be comforted).G4 for all events: ER visit or hospitalisation & were classified by investigator or medically qualified person. Events reported as AEs in CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. N=participants evaluable for this endpoint & n=participants evaluable for specified rows.

End point type	Primary

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[70] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Phase 2/3: Placebo: 6 months to <2 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	459	222		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever:>=38.0 (n=459,222)	6.1 (4.1 to 8.7)	5.9 (3.2 to 9.8)		
Fever:38.0 to 38.4 deg C (n=459,222)	3.3 (1.8 to 5.3)	3.2 (1.3 to 6.4)		
Fever: >38.4 to 38.9 deg C (n=459,222)	1.3 (0.5 to 2.8)	1.8 (0.5 to 4.5)		
Fever: >38.9 to 40.0 deg C (n=459,222)	1.1 (0.4 to 2.5)	0.9 (0.1 to 3.2)		
Fever: >40.0 deg C (n=459,222)	0.4 (0.1 to 1.6)	0 (0.0 to 1.6)		
Decreased appetite: Any (n=455,222)	19.6 (16.0 to 23.5)	13.1 (8.9 to 18.2)		
Decreased appetite: Mild (n=455,222)	11.2 (8.5 to 14.5)	7.2 (4.2 to 11.4)		
Decreased appetite: Moderate (n=455,222)	7.5 (5.2 to 10.3)	5.9 (3.2 to 9.8)		
Decreased appetite: Severe (n=455,222)	0.9 (0.2 to 2.2)	0 (0.0 to 1.6)		
Decreased appetite: Grade 4 (n=455,222)	0 (0.0 to 0.8)	0 (0.0 to 1.6)		
Drowsiness: Any (n=455,222)	21.5 (17.8 to 25.6)	12.2 (8.2 to 17.2)		
Drowsiness: Mild (n=455,222)	15.8 (12.6 to 19.5)	9.0 (5.6 to 13.6)		
Drowsiness: Moderate (n=455,222)	5.3 (3.4 to 7.7)	2.7 (1.0 to 5.8)		
Drowsiness: Severe (n=455,222)	0.4 (0.1 to 1.6)	0.5 (0.0 to 2.5)		
Drowsiness: Grade 4 (n=455,222)	0 (0.0 to 0.8)	0 (0.0 to 1.6)		
Irritability: Any (n=455,222)	42.0 (37.4 to 46.7)	36.9 (30.6 to 43.7)		
Irritability: Mild (n=455,222)	15.8 (12.6 to 19.5)	15.3 (10.8 to 20.7)		
Irritability: Moderate (n=455,222)	25.7 (21.8 to 30.0)	21.6 (16.4 to 27.6)		
Irritability: Severe (n=455,222)	0.4 (0.1 to 1.6)	0 (0.0 to 1.6)		

Irritability: Grade 4 (n=455,222)	0 (0.0 to 0.8)	0 (0.0 to 1.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=5 to <12 Years of age[71]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 1 to 1 month after dose 2 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

End point type	Primary

End point timeframe:

From Dose 1 to 1 month after Dose 2

Notes:

[71] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 2/3: Placebo: 5 to <12 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3109	1538		
Units: Percentage of participants				
number (confidence interval 95%)	10.7 (9.6 to 11.9)	9.8 (8.3 to 11.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: >=5 to <12 Years of age[72]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 3 to 1 month after dose 3 were

reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From Dose 3 to 1 month after Dose 3

Notes:

[72] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age			
Subject group type	Reporting group			
Number of subjects analysed	2408			
Units: Percentage of participants				
number (confidence interval 95%)	8.0 (7.0 to 9.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2 : >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2 : >=5 to <12 Years of age[73]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention. 'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From Dose 1 to 6 months after Dose 2

Notes:

[73] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 2/3: Placebo: 5 to <12 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3109	1538		
Units: Percentage of participants				
number (confidence interval 95%)	0.3 (0.1 to 0.5)	0.1 (0.0 to 0.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=2 to <5 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=2 to <5 Years of age[74]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 1 to 1 month after dose 2 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From Dose 1 to 1 month after Dose 2

Notes:

[74] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 2/3: Placebo: 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2350	1173		
Units: Percentage of participants				
number (confidence interval 95%)	13.1 (11.8 to 14.6)	13.0 (11.1 to 15.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: >=5 to <12 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: >=5 to <12 Years of age[75]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing

hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention.'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From Dose 3 to 6 months after Dose 3 (Approximately 6 months)

Notes:

[75] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age			
Subject group type	Reporting group			
Number of subjects analysed	2408			
Units: Percentage of participants				
number (confidence interval 95%)	0.4 (0.2 to 0.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: >=2 to <5 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: >=2 to <5 Years of age[76]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention. 'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From Dose 1 to 6 months after Dose 2

Notes:

[76] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 2/3: Placebo: 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2350	1173		
Units: Percentage of participants				
number (confidence interval 95%)	0.5 (0.2 to 0.8)	0.9 (0.4 to 1.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3:>=2 to <5 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3:>=2 to <5 Years of age[77]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 3 to 1 month after dose 3 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From Dose 3 to 1 month after Dose 3

Notes:

[77] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 2/3: Placebo: 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	863	405		
Units: Percentage of participants				
number (confidence interval 95%)	4.5 (3.2 to 6.1)	6.4 (4.2 to 9.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3:>=2 to <5 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3:>=2 to <5 Years of age[78]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or

non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention. 'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From Dose 3 to 6 months after Dose 3 (Approximately 6 months)

Notes:

[78] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 2/3: Placebo: 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	863	405		
Units: Percentage of participants				
number (confidence interval 95%)	0.3 (0.1 to 1.0)	0 (0.0 to 0.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2 : >=6 Months to <2 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2 : >=6 Months to <2 Years of age[79]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 1 to 1 month after dose 2 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From Dose 1 to 1 month after Dose 2

Notes:

[79] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Phase 2/3: Placebo: 6 months to <2 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1447	718		
Units: Percentage of participants				
number (confidence interval 95%)	21.5 (19.4 to 23.7)	19.9 (17.1 to 23.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2 : >=6 Months to <2 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2 : >=6 Months to <2 Years of age[80]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention. 'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From Dose 1 to 6 months after Dose 2

Notes:

[80] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Phase 2/3: Placebo: 6 months to <2 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1447	718		
Units: Percentage of participants				
number (confidence interval 95%)	1.7 (1.1 to 2.5)	2.4 (1.4 to 3.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3 : >=6 Months to <2 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3 : >=6 Months to <2 Years of age[81]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 3 to 1 month after dose 3 were

reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From Dose 3 to 1 month after Dose 3

Notes:

[81] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Phase 2/3: Placebo: 6 months to <2 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	483	237		
Units: Percentage of participants				
number (confidence interval 95%)	10.4 (7.8 to 13.4)	7.6 (4.6 to 11.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3 : >=6 Months to <2 Years of age

End point title	Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3 : >=6 Months to <2 Years of age[82]

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention. 'N' signifies participants evaluable for this endpoint.

End point type	Primary

End point timeframe:

From Dose 3 to 6 months after Dose 3 (Approximately 6 months)

Notes:

[82] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

End point values	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Phase 2/3: Placebo: 6 months to <2 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	483	237		
Units: Percentage of participants				

number (confidence interval 95%)	0.2 (0.0 to 1.1)	0 (0.0 to 1.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2/3: Geometric Mean Ratio (GMR) for SARS-CoV-2 Neutralizing Titers in Participants >=5 to <12 Years of age to Participants 16 to 25 Years of age From Phase 2/3 of the C4591001 Study:1 Month After Dose 2:Participants Without Evidence of Infection

End point title	Phase 2/3: Geometric Mean Ratio (GMR) for SARS-CoV-2 Neutralizing Titers in Participants >=5 to <12 Years of age to Participants 16 to 25 Years of age From Phase 2/3 of the C4591001 Study:1 Month After Dose 2:Participants Without Evidence of Infection

End point description:

GMRs and the corresponding 2-sided CIs were calculated by exponentiating the mean difference of the logarithm of the titers and the corresponding CIs(based on student t distribution).Assay results below the lower limit of quantitation(LLOQ))were set to 0.5*LLOQ.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants of the age 16 to 25 years who received 2 doses of original BNT162b2 30 mcg who had no serological or virological evidence of past SARS-CoV-2 infection and had no medical history of COVID-19 were also included.Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised,had a valid and determinate immunogenicity result within 28-42 days after the study vaccination,and had no other important protocol deviations as determined by the clinician.N=participants evaluable.GMT is reported in descriptive analysis & GMR is reported under statistical analysis.

End point type	Primary

End point timeframe:

C4591007 (>=5 to <12 years):1 month after Dose 2 and C4591001 control arm (16-25 years):1 month after Dose 2

End point values	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age	Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	264	253		
Units: Titers				
geometric mean (confidence interval 95%)	1197.6 (1106.1 to 1296.6)	1146.5 (1045.5 to 1257.2)		

Statistical analyses

Statistical analysis title	Geometric Mean Ratio

Statistical analysis description:

Phase 2/3: Geometric Mean Ratio for SARS-CoV-2 Neutralizing Titers in Participants >=5 to <12 Years of age to Participants 16 to 25 Years of age from Phase 2/3 of the C4591001 Study : 1 Month after Dose 2

Comparison groups	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years
Number of subjects included in analysis	517
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.18

Primary: Phase 2/3: GMR for SARS-CoV-2 Neutralizing Titers in Participants >=2 to <5 Years of age to Participants 16 to 25 Years of age From Phase 2/3 of the C4591001 Study : 1 Month After Dose 2: Participants Without Evidence of Infection

End point title	Phase 2/3: GMR for SARS-CoV-2 Neutralizing Titers in Participants >=2 to <5 Years of age to Participants 16 to 25 Years of age From Phase 2/3 of the C4591001 Study : 1 Month After Dose 2: Participants Without Evidence of Infection

End point description:

GMRs and the corresponding 2-sided CIs were calculated by exponentiating the mean difference of the logarithm of the titers and the corresponding CIs(based on student t distribution).Assay results below the lower limit of quantitation(LLOQ))were set to 0.5*LLOQ.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants of the age 16 to 25 years who received 2 doses of original BNT162b2 30 mcg who had no serological or virological evidence of past SARS-CoV-2 infection and had no medical history of COVID-19 were also included.Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised,had a valid and determinate immunogenicity result within 28-42 days after the study vaccination,and had no other important protocol deviations as determined by the clinician.N=participants evaluable.GMT is reported in descriptive analysis & GMR is reported under statistical analysis.

End point type	Primary

End point timeframe:

C4591007 (>=2 to <5 years):1 month after Dose 2 and C4591001 control arm (16-25 years):1 month after Dose 2

End point values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	243	252		
Units: Titers				

geometric mean (confidence interval 95%)	763.9 (688.5 to 847.5)	1255.4 (1131.2 to 1393.3)		

Statistical analyses

Statistical analysis title	Geometric Mean Ratio
Statistical analysis description:	
Geometric Mean Ratio for SARS-CoV-2 Neutralizing Titers in Participants >=2 to <5 Years of age to Participants 16 to 25 Years of age from Phase 2/3 of the C4591001 study : at 1 Month after Dose- 2 Phase 2/3	
Comparison groups	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years
Number of subjects included in analysis	495
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	0.7

Primary: Phase 2/3: Difference in Percentage of Participants who Achieved Seroresponse in >=5 to <12 Years of age and 16 to 25 Years of age From Phase 2/3 of the C4591001 Study : 1 Month After Dose 2: Participants Without Evidence of Infection

End point title	Phase 2/3: Difference in Percentage of Participants who Achieved Seroresponse in >=5 to <12 Years of age and 16 to 25 Years of age From Phase 2/3 of the C4591001 Study : 1 Month After Dose 2: Participants Without Evidence of Infection
End point description:	
Seroresponse is defined as achieving a >=4-fold rise from baseline(before Dose 1). Assay result below a postvaccination >=4*LLOQ is considered a seroresponse.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants who had no serological or virological evidence (prior to the 1-month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection were included for this analysis. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable for this endpoint. Percentage of participants with seroresponse is reported in descriptive analysis and the difference in percentage of participants is reported under statistical analysis.	
End point type	Primary
End point timeframe:	
C4591007 (>=5 to <12 years):1 month after Dose 2 and C4591001 control arm (16-25 years):1 month after Dose 2	

End point values	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age	Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	264	253		
Units: Percentage of participants				
number (confidence interval 95%)	99.2 (97.3 to 99.9)	99.2 (97.2 to 99.9)		

Statistical analyses

Statistical analysis title	Difference in Percentages

Statistical analysis description:

Difference in Percentages of Participants With Seroresponse – Participants Without Evidence of Infection up to 1 Month After Dose 2 – Immunobridging Subset – Phase 2/3 – Comparison of 5 to <12 Years of Age to Study C4591001 Phase 2/3 – 16 Through 25 Years of Age

Comparison groups	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years
Number of subjects included in analysis	517
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	2.2

Primary: Phase 2/3: Difference in Percentage of Participants who Achieved Seroresponse in >=2 to <5 Years of age and 16 to 25 Years of age From Phase 2/3 of the C4591001 Study : 1 Month After Dose 2: Participants Without Evidence of Infection

End point title	Phase 2/3: Difference in Percentage of Participants who Achieved Seroresponse in >=2 to <5 Years of age and 16 to 25 Years of age From Phase 2/3 of the C4591001 Study : 1 Month After Dose 2: Participants Without Evidence of Infection

End point description:

Seroresponse is defined as achieving a >=4-fold rise from baseline(before Dose 1). Assay result below a postvaccination >=4*LLOQ is considered a seroresponse.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants who had no serological or virological evidence (prior to the 1-month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection were included for this analysis. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable for this endpoint. Percentage of participants with seroresponse is reported in descriptive analysis and the difference in percentage of participants is reported under statistical analysis.

End point type	Primary

End point timeframe:

C4591007 (>=2 to <5 years):1 month after Dose 2 and C4591001 control arm (16-25 years):1 month after Dose 2

End point values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	243	251		
Units: Percentage of Participants				
number (confidence interval 95%)	96.7 (93.6 to 98.6)	97.6 (94.9 to 99.1)		

Statistical analyses

Statistical analysis title	Difference in Percentage
Statistical analysis description:	
Phase 2/3: Difference in Percentage of Participants who Achieved Seroresponse in >=2 to <5 Years of age and 16 to 25 Years of age from Phase 2/3 of the C4591001 study : 1 Month after Dose 2	
Comparison groups	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years
Number of subjects included in analysis	494
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentage
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.3
upper limit	2.3

Primary: Phase 2/3: Difference in Percentage of Participants who Achieved Seroresponse in >=6 Months to <2 Years of age and 16 to 25 Years of age From Phase 2/3 of the C4591001 Study: 1 Month After Dose 2: Participants Without Evidence of Infection

End point title	Phase 2/3: Difference in Percentage of Participants who Achieved Seroresponse in >=6 Months to <2 Years of age and 16 to 25 Years of age From Phase 2/3 of the C4591001 Study: 1 Month After Dose 2: Participants Without Evidence of Infection

End point description:

Seroresponse is defined as achieving a >=4-fold rise from baseline(before Dose 1). Assay result below a postvaccination >=4*LLOQ is considered a seroresponse.Results include those from a comparator group

of C4591001(NCT04368728)Phase 2/3 participants who had no serological or virological evidence (prior to the 1-month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection were included for this analysis. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable for this endpoint. Percentage of participants with seroresponse is reported in descriptive analysis and the difference in percentage of participants is reported under statistical analysis.

End point type	Primary

End point timeframe:

C4591007 (>=6 months to <2 years):1 month after Dose 2 and C4591001 control arm (16-25 years):1 month after Dose 2

End point values	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	245	238		
Units: Percentage of Participants				
number (confidence interval 95%)	98.0 (95.3 to 99.3)	96.2 (92.9 to 98.3)		

Statistical analyses

Statistical analysis title	Difference in Percentage

Statistical analysis description:

Phase 2/3: Difference in Percentage of Participants who Achieved Seroresponse in >=6 Months to <2 Years of age and 16 to 25 Years of age from Phase 2/3 of the C4591001 study : 1 Month after Dose 2

Comparison groups	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years
Number of subjects included in analysis	483
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentage
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	5.2

Primary: Phase 2/3: GMR for SARS-CoV-2 Neutralizing Titers in Participants >=6 Months to <2 Years of age to Participants 16 to 25 Years of age From Phase 2/3 of the C4591001 Study : 1 Month After Dose 2: Participants Without Evidence of Infection

End point title	Phase 2/3: GMR for SARS-CoV-2 Neutralizing Titers in Participants >=6 Months to <2 Years of age to Participants 16 to 25 Years of age From Phase 2/3 of the C4591001 Study : 1 Month After Dose 2: Participants Without Evidence of Infection

End point description:

GMRs and the corresponding 2-sided CIs were calculated by exponentiating the mean difference of the logarithm of the titers and the corresponding CIs(based on student t distribution).Assay results below the lower limit of quantitation(LLOQ))were set to 0.5*LLOQ.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants of the age 16 to 25 years who received 2 doses of original BNT162b2 30 mcg who had no serological or virological evidence of past SARS-CoV-2 infection and had no medical history of COVID-19 were also included.Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised,had a valid and determinate immunogenicity result within 28-42 days after the study vaccination,and had no other important protocol deviations as determined by the clinician.N=participants evaluable.GMT is reported in descriptive analysis & GMR is reported under statistical analysis.

End point type	Primary

End point timeframe:

C4591007 (>=6 months to <2 years):1 month after Dose 2 and C4591001 control arm (16-25 years):1 month after Dose 2

End point values	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	245	238		
Units: Titers				
geometric mean (confidence interval 95%)	979.7 (893.2 to 1074.6)	946.8 (850.8 to 1053.7)		

Statistical analyses

Statistical analysis title	Geometric Mean Ratio

Statistical analysis description:

Phase 2/3: Geometric Mean Ratio for SARS-CoV-2 Neutralizing Titers in Participants >=6 Months to <2 Years of age to Participants 16 to 25 Years of age from Phase 2/3 of the C4591001 study : at 1 Month after Dose 2

Comparison groups	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years
Number of subjects included in analysis	483
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric Mean Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.19

Primary: Phase 2/3:GMR for SARS-CoV-2 Neutralizing Titers at 1 Month After Dose 3 in Participants Aged >=2 to <5 Years to Those at 1 Month After Dose 2 in Participants Aged 16 to 25 Years From Phase 2/3 of C4591001 Study:Participants Without Evidence of Infection

End point title	Phase 2/3:GMR for SARS-CoV-2 Neutralizing Titers at 1 Month After Dose 3 in Participants Aged >=2 to <5 Years to Those at 1 Month After Dose 2 in Participants Aged 16 to 25 Years From Phase 2/3 of C4591001 Study:Participants Without Evidence of Infection

End point description:

GMRs and the corresponding 2-sided CIs were calculated by exponentiating the mean difference of the logarithm of the titers and the corresponding CIs(based on student t distribution).Assay results below the lower limit of quantitation(LLOQ))were set to 0.5*LLOQ.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants of the age 16 to 25 years who received 2 doses of original BNT162b2 30 mcg who had no serological or virological evidence of past SARS-CoV-2 infection and had no medical history of COVID-19 were also included.Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised,had a valid and determinate immunogenicity result within 28-42 days after the study vaccination,and had no other important protocol deviations as determined by the clinician.N=participants evaluable.GMT is reported in descriptive analysis & GMR is reported under statistical analysis.

End point type	Primary

End point timeframe:

C4591007 (>=2 to <5 years):1 month after Dose 2 and C4591001 control arm (16-25 years):1 month after Dose 2

End point values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	143	170		
Units: Titers				
geometric mean (confidence interval 95%)	1535.2 (1388.2 to 1697.8)	1180.0 (1066.6 to 1305.4)		

Statistical analyses

Statistical analysis title	Geometric Mean Ratio

Statistical analysis description:

Phase 2/3: Geometric Mean Ratio for SARS-CoV-2 Neutralizing Titers at 1 Month after dose 3 in Participants >=2 to <5 Years of age to those at 1 month after Dose 2 in participants 16 to 25 years of age from Phase 2/3 of the C4591001 study

Comparison groups	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years

Number of subjects included in analysis	313
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric Mean Ratio
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.13
upper limit	1.5

Primary: Phase 2/3:Difference in Percentage of Participants With Seroresponse in 2 to <5 Years of Age Compared With Study C4591001 Phase 2/3 16 Through 25 Years of Age: Participants Without Evidence of Infection

End point title	Phase 2/3:Difference in Percentage of Participants With Seroresponse in 2 to <5 Years of Age Compared With Study C4591001 Phase 2/3 16 Through 25 Years of Age: Participants Without Evidence of Infection

End point description:

Seroresponse is defined as achieving a >=4-fold rise from baseline(before Dose 1). Assay result below a postvaccination >=4*LLOQ is considered a seroresponse.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants who had no serological or virological evidence (prior to the 1-month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection were included for this analysis. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable for this endpoint. Percentage of participants with seroresponse is reported in descriptive analysis and the difference in percentage of participants is reported under statistical analysis.

End point type	Primary

End point timeframe:

C4591007 (>=2 to <5 years):1 month after Dose 3 and C4591001 control arm (16-25 years):1 month after Dose 2

End point values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	141	170		
Units: Percentage of participants				
number (confidence interval 95%)	100.0 (97.4 to 100.0)	98.8 (95.8 to 99.9)		

Statistical analyses

Statistical analysis title	Difference in Percentages

Statistical analysis description:

Phase 2/3: Difference in Percentages of Participants With Seroresponse – Participants Without Evidence of Infection – Immunobridging Subset – Comparison of Study C4591007 Phase 2/3 2 to <5 Years of Age (1 Month After Dose 3) and Study C4591001 Phase 2/3 16 Through 25 Years of Age (1 Month After Dose 2)

Comparison groups	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years
Number of subjects included in analysis	311
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentages
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	4.2

Primary: Phase 2/3:Difference in Percentage of Participants With Seroresponse in 6 Months to <2 Years (1 Month After Dose 3) Compared With Study C4591001 Phase 2/3 16 Through 25 Years (1 Month After Dose 2): Participants Without Evidence of Infection

End point title	Phase 2/3:Difference in Percentage of Participants With Seroresponse in 6 Months to <2 Years (1 Month After Dose 3) Compared With Study C4591001 Phase 2/3 16 Through 25 Years (1 Month After Dose 2): Participants Without Evidence of Infection

End point description:

Seroresponse is defined as achieving a >=4-fold rise from baseline(before Dose 1). Assay result below a postvaccination >=4*LLOQ is considered a seroresponse.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants who had no serological or virological evidence (prior to the 1-month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection were included for this analysis. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable for this endpoint. Percentage of participants with seroresponse is reported in descriptive analysis and the difference in percentage of participants is reported under statistical analysis.

End point type	Primary

End point timeframe:

C4591007 (>=6 months to <2 years):1 month after Dose 3 and C4591001 control arm (16-25 years):1 month after Dose 2

End point values	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years		

Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	80	170		
Units: Percentage of participants				
number (confidence interval 95%)	100.0 (95.5 to 100.0)	98.8 (95.8 to 99.9)		

Statistical analyses

Statistical analysis title	Difference in Percentages

Statistical analysis description:

Phase 2/3: Difference in Percentages of Participants With Seroresponse – Participants Without Evidence of Infection – Immunobridging Subset – Comparison of Study C4591007 Phase 2/3 6 Months to <2 Years of Age (1 Month After Dose 3) and Study C4591001 Phase 2/3 16 Through 25 Years of Age (1 Month After Dose 2) – Evaluable Immunogenicity Population

Comparison groups	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years
Number of subjects included in analysis	250
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in percentage
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	4.2

Primary: Phase 2/3:GMR for SARS-CoV-2 Neutralizing Titers at 1 Month After Dose 3 in Participants Aged 6 Months to 2 Years to Those at 1 Month After Dose 3 in Participants Aged 16 to 25 Years From Phase 2/3 of C4591001:Participants Without Evidence of Infection

End point title	Phase 2/3:GMR for SARS-CoV-2 Neutralizing Titers at 1 Month After Dose 3 in Participants Aged 6 Months to 2 Years to Those at 1 Month After Dose 3 in Participants Aged 16 to 25 Years From Phase 2/3 of C4591001:Participants Without Evidence of Infection

End point description:

GMRs and the corresponding 2-sided CIs were calculated by exponentiating the mean difference of the logarithm of the titers and the corresponding CIs(based on student t distribution).Assay results below the lower limit of quantitation(LLOQ))were set to 0.5*LLOQ.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants of the age 16 to 25 years who received 2 doses of original BNT162b2 30 mcg who had no serological or virological evidence of past SARS-CoV-2 infection and had no medical history of COVID-19 were also included.Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised,had a valid and determinate immunogenicity result within 28-42 days after the study vaccination,and had no other important protocol deviations as determined by the clinician.N=participants evaluable.GMT is reported in descriptive analysis & GMR is reported under statistical analysis.

End point type	Primary

End point timeframe:

C4591007 (>=2 to <5 years):1 month after Dose 3 and C4591001 control arm (16-25 years):1 month after Dose 2

End point values	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	82	170		
Units: Titers				
geometric mean (confidence interval 95%)	1406.5 (1211.3 to 1633.1)	1180.0 (1066.6 to 1305.4)		

Statistical analyses

Statistical analysis title	Geometric Mean Ratio
Statistical analysis description:	
Phase 2/3: Geometric Mean Ratio for SARS-CoV-2 Neutralizing Titers at 1 Month after dose 3 in Participants 6 Months to <2 Years of age to those at 1 month after Dose 3 in participants 16 to 25 years of age from Phase 2/3 of the C4591001 study	
Comparison groups	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years
Number of subjects included in analysis	252
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio
Point estimate	1.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	1
upper limit	1.42

Secondary: Phase 1: Geometric Mean Titers (GMTs) of Severe Acute Respiratory Syndrome Coronavirus 2 Neutralizing Titers at 7 Days After Dose 2: >=6 Months to <2 Years of age: Participants Without Evidence of Infection

End point title	Phase 1: Geometric Mean Titers (GMTs) of Severe Acute Respiratory Syndrome Coronavirus 2 Neutralizing Titers at 7 Days After Dose 2: >=6 Months to <2 Years of age: Participants Without Evidence of Infection

End point description:

GMT of SARS-CoV-2 neutralizing titers after the study vaccination was reported in this endpoint. GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs(based on Student's t distribution).Assay results below the LLOQ were set to 0.5*LLOQ. Evaluable Immunogenicity Population consisted of all eligible randomized participants who received 2 doses with the same dose level to which they were randomized, with Dose 2 received within the predefined window, had at least 1 valid and determinate immunogenicity result after Dose 2 from

the blood sample collected within an appropriate window after Dose 2(within 6-8 days after Dose 2 for Phase 1), and had no other important protocol deviations as determined by the clinician.Participants without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Day 7 post Dose 2

End point values	Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Titers				
geometric mean (confidence interval 95%)	1643.8 (1151.3 to 2347.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: GMTs of Severe Acute Respiratory Syndrome Coronavirus 2 Neutralizing Titers at 7 Days After Dose 2: >=2 to <5 Years of age: Participants Without Evidence of Infection

End point title	Phase 1: GMTs of Severe Acute Respiratory Syndrome Coronavirus 2 Neutralizing Titers at 7 Days After Dose 2: >=2 to <5 Years of age: Participants Without Evidence of Infection

End point description:

GMT of SARS-CoV-2 neutralizing titers after the study vaccination was reported in this endpoint. GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs(based on Student's t distribution).Assay results below the LLOQ were set to 0.5*LLOQ. Evaluable Immunogenicity Population consisted of all eligible randomized participants who received 2 doses with the same dose level to which they were randomized, with Dose 2 received within the predefined window, had at least 1 valid and determinate immunogenicity result after Dose 2 from the blood sample collected within an appropriate window after Dose 2(within 6-8 days after Dose 2 for Phase 1), and had no other important protocol deviations as determined by the clinician.Participants without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Day 7 post Dose 2

End point values	Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	29		
Units: Titers				
geometric mean (confidence interval 95%)	1350.4 (973.1 to 1873.9)	2059.5 (1679.1 to 2526.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: GMTs of Severe Acute Respiratory Syndrome Coronavirus 2 Neutralizing Titers at 7 Days After Dose 2: >=5 to <12 Years of age: Participants Without Evidence of Infection

End point title	Phase 1: GMTs of Severe Acute Respiratory Syndrome Coronavirus 2 Neutralizing Titers at 7 Days After Dose 2: >=5 to <12 Years of age: Participants Without Evidence of Infection

End point description:

GMT of SARS-CoV-2 neutralizing titers after the study vaccination was reported in this endpoint. GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs(based on Student's t distribution).Assay results below the LLOQ were set to 0.5*LLOQ. Evaluable Immunogenicity Population consisted of all eligible randomized participants who received 2 doses with the same dose level to which they were randomized, with Dose 2 received within the predefined window, had at least 1 valid and determinate immunogenicity result after Dose 2 from the blood sample collected within an appropriate window after Dose 2(within 6-8 days after Dose 2 for Phase 1), and had no other important protocol deviations as determined by the clinician.Participants without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Day 7 post Dose 2

End point values	Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: Titers				
geometric mean (confidence interval 95%)	4162.6 (2584.7 to 6704.0)	4583.4 (2802.9 to 7494.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2/3: Geometric Mean Titers – NT50: Immunogenicity Set – 5 to <12 Years of Age:Dose 3 and 1 Month After Dose 3 :Participants Without Evidence of Infection

End point title	Phase 2/3: Geometric Mean Titers – NT50: Immunogenicity Set – 5 to <12 Years of Age:Dose 3 and 1 Month After Dose 3 :Participants Without Evidence of Infection

End point description:

GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on Student's t distribution). Assay results below the LLOQ were set to 0.5*LLOQ. Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection or had no medical history of COVID-19. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Dose 3 set: Pre-dose 3 and 1 month after Dose 3

End point values	Phase 2/3: BNT162b2 (10 mcg) 3-Dose Set			
Subject group type	Subject analysis set			
Number of subjects analysed	67			
Units: Titers				
number (confidence interval 95%)				
Pre-dose 3	271.0 (229.1 to 320.6)			
1 month after dose 3	2720.9 (2280.1 to 3247.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2/3: Geometric Mean Titers – NT50: Immunogenicity Set – 5 to <12 Years of Age: Dose 1 to 1 Month After Dose 2:Participants Without Evidence of Infection

End point title	Phase 2/3: Geometric Mean Titers – NT50: Immunogenicity Set – 5 to <12 Years of Age: Dose 1 to 1 Month After Dose 2:Participants Without Evidence of Infection

End point description:

GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on Student's t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ. Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection or had no medical history of COVID-19. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the

clinician.'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Pre-dose 1 and 1 month after Dose 2

End point values	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 2/3: Placebo: 5 to <12 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	264	130		
Units: Titers				
geometric mean (confidence interval 95%)				
Pre-dose 1	10.1 (9.9 to 10.3)	10.0 (10.0 to 10.0)		
1 month after Dose 2	1197.6 (1106.1 to 1296.6)	10.7 (9.7 to 11.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2/3: Geometric Mean Titers – NT50:2 to <5 Years of Age: Pre-Dose 1, Pre-Dose 3 and 1 Month After Dose 3: Participants Without Evidence of Infection

End point title	Phase 2/3: Geometric Mean Titers – NT50:2 to <5 Years of Age: Pre-Dose 1, Pre-Dose 3 and 1 Month After Dose 3: Participants Without Evidence of Infection

End point description:

GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on Student's t distribution). Assay results below the LLOQ were set to 0.5 *LLOQ. Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection or had no medical history of COVID-19. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.
'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Pre-Dose 1, Pre-Dose 3 and 1 Month After Dose 3

End point values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 2/3: Placebo: 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	59		
Units: Titers				
number (confidence interval 95%)				
Pre-dose 1 (n=141, 57)	20.7 (20.3 to 21.2)	20.5 (20.5 to 20.5)		
Pre-dose 3 (n=143, 59)	401.1 (361.7 to 444.7)	20.9 (20.1 to 21.8)		
1 month after dose 3 (n=143, 59)	1535.2 (1388.2 to 1697.8)	22.9 (19.5 to 26.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2/3: Geometric Mean Titers- NT50:6 Months to <2 Years of Age: Pre-Dose 1, Pre-Dose 3 and 1 Month After Dose 3: Participants Without Evidence of Infection

End point title	Phase 2/3: Geometric Mean Titers- NT50:6 Months to <2 Years of Age: Pre-Dose 1, Pre-Dose 3 and 1 Month After Dose 3: Participants Without Evidence of Infection

End point description:

GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on Student's t distribution). Assay results below the LLOQ were set to 0.5*LLOQ. Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection or had no medical history of COVID-19. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.
'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Pre-Dose 1, Pre-Dose 3 and 1 Month After Dose 3

End point values	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Phase 2/3: Placebo: 6 months to <2 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	82	49		
Units: Titer				
number (confidence interval 95%)				
Pre- dose 1 (80, 48)	20.8 (20.2 to 21.5)	20.5 (20.5 to 20.5)		
Pre-dose 3 (81, 49)	317.0 (268.8 to 373.9)	24.2 (19.7 to 29.8)		

1 Month After Dose 3 (82, 49)	1406.5 (1211.3 to 1633.1)	22.3 (18.8 to 26.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2/3: GMFR of SARS-CoV-2 Neutralizing Titers From Before Dose 1 to Each Subsequent Time Point After Dose 3: >=2 to 5 Years of age: Participants Without Evidence of Infection

End point title	Phase 2/3: GMFR of SARS-CoV-2 Neutralizing Titers From Before Dose 1 to Each Subsequent Time Point After Dose 3: >=2 to 5 Years of age: Participants Without Evidence of Infection

End point description:

GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs(based on the Student t distribution). Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection and had no medical history of COVID-19 infection.Assay results below the LLOQ were set to 0.5*LLOQ in the analysis.Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised,had a valid and determinate immunogenicity result within 28-42 days after the study vaccination,and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable in this endpoint.

End point type	Secondary

End point timeframe:

Pre-dose 3, 1 Month After Dose 3

End point values	Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age	Phase 2/3: Placebo: 2 to <5 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	141	57		
Units: Fold rise				
geometric mean (confidence interval 95%)				
Pre-dose 3	19.2 (17.4 to 21.3)	1.0 (1.0 to 1.0)		
1 month after Dose 3	73.3 (66.3 to 81.1)	1.1 (0.9 to 1.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2/3: Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Neutralizing Titers From Dose 1 to 1 Month After Dose 2: >=5 to 12 Years of age: Participants Without Evidence of Infection

End point title	Phase 2/3: Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Neutralizing Titers From Dose 1 to 1 Month After Dose 2: >=5 to 12 Years of age: Participants Without Evidence of Infection

End point description:

GMFR of SARS-CoV-2 neutralizing titers from dose 1 to 1 month after dose 2 were reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection or had no medical history of COVID-19. Assay results below the LLOQ were set to 0.5* LLOQ in the analysis. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

From Dose 1 to 1 month after Dose 2

End point values	Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age	Phase 2/3: Placebo: 5 to <12 years of age		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	264	130		
Units: Fold rise				
geometric mean (confidence interval 95%)	118.2 (109.2 to 127.9)	1.1 (1.0 to 1.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2/3:GMFR of SARS-CoV-2 Neutralizing Titers From Dose 3 to 1 Month After Dose 3: >=5 to 12 Years of age: Participants Without Evidence of Infection

End point title	Phase 2/3:GMFR of SARS-CoV-2 Neutralizing Titers From Dose 3 to 1 Month After Dose 3: >=5 to 12 Years of age: Participants Without Evidence of Infection

End point description:

GMFR of SARS-CoV-2 neutralizing titers from before Dose 3 to 1 month after Dose were reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ in the analysis. Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection or had no medical history of COVID-19. Evaluable immunogenicity population included all eligible randomized participants who received the study interventions to which they were randomized, had a valid and determined immunogenicity result within 28-42 days after Dose 3, and had no other important protocol deviations as determined by the clinicians. 'N' = participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Before dose 1 to 1 month after dose 2, pre-dose 3 and 1 month after dose 3

End point values	Phase 2/3: BNT162b2 (10 mcg) 3-Dose Set			
Subject group type	Subject analysis set			
Number of subjects analysed	67			
Units: Fold rise				
geometric mean (confidence interval 95%)	10.0 (8.1 to 12.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2/3: GMFR of SARS-CoV-2 Neutralizing Titers From Before Dose 1 to Each Subsequent Time Point After Dose 3: >=6 Months to 2 Years of age: Participants Without Evidence of Infection

End point title	Phase 2/3: GMFR of SARS-CoV-2 Neutralizing Titers From Before Dose 1 to Each Subsequent Time Point After Dose 3: >=6 Months to 2 Years of age: Participants Without Evidence of Infection

End point description:

GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ in the analysis. Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection prior to the 1-month post–Dose 2. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.
'N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Pre-dose 3, 1 Month After Dose 3

End point values	Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age	Phase 2/3: Placebo: 6 months to <2 years		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	48		
Units: Fold rise				
geometric mean (confidence interval 95%)				
Pre-dose 3 (79,48)	15.4 (12.9 to 18.3)	1.2 (1.0 to 1.5)		
1 month after Dose 3 (80,48)	68.4 (58.2 to 80.4)	1.1 (0.9 to 1.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2/3: Confirmed COVID-19 Cases From 7 Days After Dose 2 to Prior to Dose 3 per 1000 Person-Years of Blinded Follow-up in Participants Without Serological or Virological Evidence: >=5 to <12 Years of age

End point title	Phase 2/3: Confirmed COVID-19 Cases From 7 Days After Dose 2 to Prior to Dose 3 per 1000 Person-Years of Blinded Follow-up in Participants Without Serological or Virological Evidence: >=5 to <12 Years of age

End point description:

Number of confirmed COVID-19 cases from 7 days after dose 2 to prior to dose 3 without the evidence of infection were reported in this endpoint. Evaluable efficacy population included all eligible randomised subjects who received all vaccination(s) as randomized, with Dose 2 received within the predefined window (within 19-42 days after Dose 1) and have no other important protocol deviations as determined by the clinician on or before 7 days after Dose 2.

End point type	Secondary

End point timeframe:

From 7 days after Dose 2 to prior to dose 3 (Surveillance time [1000 person-years]: BNT162b2 - 0.591; Placebo - 0.292)

End point values	Ph2/3:BNT162b2 3 mcg 5-<12Y:WoEI:evaluable efficacy(3-dose)set	Phase 2/3:Placebo 5 to <12Y:WoEI:evaluable efficacy(3-		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2703	1348		
Units: Cases				
number (not applicable)	10	42		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2/3: Confirmed COVID-19 Cases From 7 Days After Dose 2 to prior to Dose 3 per 1000 Person-Years of Blinded Follow-up in Participants With or Without Serological or Virological Evidence: >=5 to <12 Years of age

End point title	Phase 2/3: Confirmed COVID-19 Cases From 7 Days After Dose 2 to prior to Dose 3 per 1000 Person-Years of Blinded Follow-up in Participants With or Without Serological or Virological Evidence: >=5 to <12 Years of age

End point description:

Number of confirmed COVID-19 cases from 7 days after dose 2 to prior to dose 3 with or without the evidence of infection were reported in this endpoint. Evaluable efficacy population included all eligible randomised subjects who received all vaccination(s) as randomized, with Dose 2 received within the predefined window (within 19-42 days after Dose 1) and have no other important protocol deviations as determined by the clinician on or before 7 days after Dose 2.

End point type	Secondary

End point timeframe:

From 7 Days After Dose 2 to prior to dose 3 (Surveillance time [1000 person-years]: BNT162b2 - 0.653; Placebo - 0.326)

End point values	Phase 2/3:BNT162b2 3 mcg 5-<12Y:evaluable efficacy(3-dose)set	Phase 2/3:Placebo 5-<12Y:evaluable efficacy(3-dose)set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3108	1511		
Units: Cases				
number (not applicable)	12	42		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2/3: Confirmed COVID-19 Cases From 7 Days After Dose 3 per 1000 Person-Years of Blinded Follow-up in Participants Without Serological or Virological Evidence: >=6 Months to <5 Years of Age

End point title	Phase 2/3: Confirmed COVID-19 Cases From 7 Days After Dose 3 per 1000 Person-Years of Blinded Follow-up in Participants Without Serological or Virological Evidence: >=6 Months to <5 Years of Age

End point description:

Number of confirmed COVID-19 cases from 7 days after dose 3 without the evidence of infection were reported in this endpoint. Evaluable efficacy population included all eligible randomised subjects who received all vaccination(s) as randomized, with Dose 3 received within the predefined window (within 19-42 days after Dose 2) and have no other important protocol deviations as determined by the clinician on or before 7 days after Dose 2. N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

From 7 Days After Dose 3 (Surveillance time [1000 person-years]: BNT162b2 - 0.124; Placebo - 0.054)

End point values	Ph2/3:BNT162b2 3mcg:6M-<5Y:WoEI:evaluable efficacy(3dose)set	Phase2/3:Placebo:6M-<5Y):WoEI:evaluable efficacy(3-dose)set		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	873	381		
Units: Cases				
number (not applicable)	13	21		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2/3: Confirmed COVID-19 Cases From 7 Days After Dose 3 per 1000 Person-Years of Blinded Follow-up in Participants With or Without Serological or Virological Evidence: >=6 Months to <5 Years of age

End point title	Phase 2/3: Confirmed COVID-19 Cases From 7 Days After Dose 3 per 1000 Person-Years of Blinded Follow-up in Participants With or Without Serological or Virological Evidence: >=6 Months to <5 Years of age

End point description:

Number of confirmed COVID-19 cases from 7 days after dose 3 without the evidence of infection were reported in this endpoint. Evaluable efficacy population included all eligible randomised subjects who received all vaccination(s) as randomized, with Dose 3 received within the predefined window (within 19-42 days after Dose 2) and have no other important protocol deviations as determined by the clinician on or before 7 days after Dose 2. N'=participants evaluable for this endpoint.

End point type	Secondary

End point timeframe:

From 7 Days After Dose 3 (Surveillance time [1000 person-years]: BNT162b2 - 0.149; Placebo - 0.067)

End point values	Phase 2/3:BNT162b2 3 mcg 6M<5Y:evaluable efficacy(3-dose)set	Phase 2/3:Placebo 6M-<5Y:evaluable efficacy(3-		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1294	612		
Units: Cases				
number (not applicable)	14	23		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Local/systemic events: Day 1 to 7 after each dose. Non SAE: Treatment emergent adverse events are reported from time of first dose of study treatment up to 1 month after last dose. SAE: From first dose to 6 months after last dose of study treatment

Adverse event reporting additional description:

Same event may appear as both non-SAE and SAE but are distinct events. An event may be categorised as serious in 1 participant and non-serious in another, or a participant may have experienced both SAE and non-SAE.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Ph2/3:BlPCFup:6M-<2Y:D1-6M After D2or Prior D3/BNT162b2 3mcg

Reporting group description:

Phase 2/3: Participants aged 6 months to <2 years were randomised to receive dose 1 of BNT162b2 3 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period were followed up to 6 month after dose 2 or prior to dose 3.

Reporting group title	Ph2/3:Bl PCFup:6 M -<2Y:D1-1M After D2/BNT162b2 3 mcg

Reporting group description:

Phase 2/3 (Ph2/3): Participants aged 6 months to <2 years (6 M -<2 Yrs) were randomised to receive dose 1 (D1) of BNT162b2 3 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period (Bl PCFup) and were followed up to 1 month after dose 2 (1M After D2).

Reporting group title	Ph2/3:Bl PCFup:6 M-<2Y:D1-1M After D2/Pb

Reporting group description:

Phase 2/3: Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo)(Pb) in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 2.

Reporting group title	Ph2/3:Bl PCFup:6M-<2Y:D3-6M After D3/Pb

Reporting group description:

Phase 2/3:Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period and were followed up to 6 month after dose 3.

Reporting group title	Ph2/3:Bl PCFup:6M-<2Y:D3-6M After D3/BNT162b2 3mcg

Reporting group description:

Phase 2/3: Participants aged 6 months to <2 years were randomised to receive dose 3 of BNT162b2 3 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period and were followed up to 6 month after dose 3.

Reporting group title	Ph2/3:Bl PCFup:6M-<2Y:D3-1M After D3/Pb

Reporting group description:

Phase 2/3:Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 3.

Reporting group title	Ph2/3:Bl PCFup:6M-<2Y:D3-1M After D3/BNT162b2 3mcg

Reporting group description:

Phase 2/3: Participants aged 6 months to <2 years were randomised to receive dose 3 of BNT162b2 3 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 3.

Reporting group title	Ph2/3:BlPCFup:6M-<2Y:D1-6M After D2 or Prior D3/Pb

Reporting group description:

Phase 2/3: Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period and were

followed up to 6 month after dose 2 or prior to dose 3.

Reporting group title	Ph2/3:Bl PCFup:5-<12Y:D1-1M After D2/ BNT162b2 10mcg

Reporting group description:

Phase 2/3:Participants aged 5 to <12 years were randomised to receive dose 1 of BNT162b2 10 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 2.

Reporting group title	Ph2/3:Bl PCFup:5-<12Y:TPG:D1-6M After D2/BNT162b2 10 mcg

Reporting group description:

Phase 2/3: Participants aged 5 to <12 years were randomised to receive dose 1 of BNT162b2 10 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period in Troponin group and were followed up to 6 month after dose 2.

Reporting group title	Ph2/3:BlPCFup:5-<12Y:TPG:D1-6MAfterD2 orPriorD3/BNT162b210mcg

Reporting group description:

Phase 2/3: Participants aged 5 to <12 years were randomised to receive dose 1 of BNT162b2 10 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period in Troponin group (TPG) and were followed up to 6 month after dose 2 or prior to dose 3.

Reporting group title	Ph2/3:Bl PCFup:2-<5Y:D3-6M After D3/Pb

Reporting group description:

Phase 2/3: Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period and were followed up to 6 month after dose 3.

Reporting group title	Ph2/3:Bl PCFup:2-<5Y:D3-6M After D3/BNT162b2 3mcg

Reporting group description:

Phase 2/3: Participants aged 2 to <5 years were randomised to receive dose 3 of BNT162b2 3 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period and were followed up to 6 month after dose 3.

Reporting group title	Ph2/3:Bl PCFup:2-<5Y:D3-1M After D3/Pb

Reporting group description:

Phase 2/3:Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 3.

Reporting group title	Ph2/3:Bl PCFup:2-<5Y:D3-1M After D3/BNT162b2 3mcg

Reporting group description:

Phase 2/3: Participants aged 2 to <5 years were randomised to receive dose 3 of BNT162b2 3 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 3.

Reporting group title	Ph2/3:BlPCFup:2-<5Y:D1-6M After D2 or Prior D3/Pb

Reporting group description:

Phase 2/3:Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period and were followed up to 6 month after dose 2 or Prior to Dose 3.

Reporting group title	Ph2/3:BlPCFup:2-<5Y:D1-6M After D2 or Prior D3/BNT162b2 3mcg

Reporting group description:

Phase 2/3:Participants aged 2 to <5 years were randomised to receive dose 1 of BNT162b2 3 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period and were followed up to 6 month after dose 2 or Prior to Dose 3.

Reporting group title	Ph2/3:Bl PCFup:5-<12Y:TPG:D1-6M After D2 or Prior D3/Pb

Reporting group description:

Phase 2/3: Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period in Troponin group and were followed up to 6 month after dose 2 or prior to dose 3.

Reporting group title	Ph2/3:BlPCFup:2-<5Y:D1-1M After D2/ BNT162b2 3mcg

Reporting group description:

Phase 2/3:Participants aged 2 to <5 years were randomised to receive dose 3 of BNT162b2 3 mcg intramuscularly in blinded placebo-controlled follow up period and were followed up from dose 1 to 1 month after dose 2.

Reporting group title	Ph2/3:Bl PCFup:2-<5Y:D1-1M After D2/Pb

Reporting group description:

Phase 2/3:Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in blinded placebo controlled follow up period and were followed from Dose 1 to 1 month after dose 2.

Reporting group title	Ph2/3:5-<12Y:TPG:D3-1M After D3/BNT162b2 10 mcg

Reporting group description:

Phase 2/3: Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) intramuscularly in Blinded Placebo and had the opportunity to receive dose 3 as BNT162b2 10 mcg in Open Label Period in Troponin group and were followed up to 1 month after dose 3.

Reporting group title	Ph2/3:5-<12Y:TPG:D3-1M After D3/BNT162b2 10 mcg

Reporting group description:

Phase 2/3: Participants aged 5 to <12 years were randomised to receive dose 3 of BNT162b2 10 mcg intramuscularly in Blinded and Open Label Period (OLP) in Troponin group and were followed up to 1 month after dose 3.

Reporting group title	Ph2/3:Bl OLP:5-<12Y:TPG:D3-6M After D3/BNT162b2 10 mcg

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) intramuscularly in Blinded Placebo and had the opportunity to receive dose 3 as BNT162b2 10 mcg in Open Label Period in Troponin group and were followed up to 6 month after dose 3.

Reporting group title	Ph1:2-<5Y:D1-1M After D2/BNT162b2 3 mcg

Reporting group description:

Phase 1: Participants aged 2 to <5 years received dose 1 of BNT162b2 3 mcg intramuscularly and were followed up to 1 month after dose 2.

Reporting group title	Ph1:6M-<2Y:D3-1M After D3/BNT162b2 3 mcg

Reporting group description:

Phase 1: Participants aged 6 months to <2 years received dose 3 of BNT162b2 3 mcg intramuscularly and were followed up to 1 month after dose 3.

Reporting group title	Ph1:6M-<2Y:D1-6M After D2/BNT162b2 3 mcg

Reporting group description:

Phase 1: Participants aged 6 months to <2 years received dose 1 of BNT162b2 3 mcg intramuscularly and were followed up to 6 month after dose 2.

Reporting group title	Ph2/3:OLP:12-<16Y:TPG:D3-1M After D3/BNT162b2 30 mcg

Reporting group description:

Phase 2/3: Participants aged 12 to <16 years were randomised to receive dose 3 of BNT162b2 30 mcg intramuscularly in open label in Troponin group and were followed up to 1 month after dose 3.

Reporting group title	Ph2/3:OLP:12-<16Y:TPG:D1-6M After D2or priorD3/BNT162b2 30mcg

Reporting group description:

Phase 2/3: Participants aged 12 to <16 years were randomised to receive dose 1 of BNT162b2 30 mcg intramuscularly in open label in Troponin group and were followed up to 6 month after dose 2 or prior to dose 3.

Reporting group title	Ph2/3:OLP:12-<16Y:TPG:D1-1M After D2/BNT162b2 30 mcg

Reporting group description:

Phase 2/3: Participants aged 12 to <16 years were randomised to receive dose 1 of BNT162b2 30 mcg intramuscularly in Open label in Troponin group and were followed up to 1 month after dose 2.

Reporting group title	Ph1:2-<5Y:D1-1M After D2/BNT162b2 10 mcg

Reporting group description:

Phase 1: Participants aged 2 to <5 years received dose 1 of BNT162b2 10 mcg intramuscularly and were followed up to 1 month after dose 2.

Reporting group title	Ph1:2-<5Y:D3-1M After D3/BNT162b2 3 mcg

Reporting group description:

Phase 1: Participants aged 2 to <5 years received dose 3 of BNT162b2 3 mcg intramuscularly and were followed up to 1 month after dose 3.

Reporting group title	Ph2/3:BlPCFup:5 -<12Y:D1-1M After D2 or PTD3/Pb

Reporting group description:

Phase 2/3:Participants aged 5 to <12 years received 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 2 or prior to dose 3.

Reporting group title	Ph2/3:BlOLP:5-<12Y:D3-1M After D3/BNT162b2 10 mcg

Reporting group description:

Participants aged 5 to <12 years were randomised to receive dose 3 as BNT162b2 10 mcg in Blinded and Open Label Period and were followed up to 1 month after dose 3.

Reporting group title	Ph2/3:BlOLP:5-<12Y:D3-1M After D3/BNT162b2 10 mcg

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) intramuscularly in Blinded Placebo and had the opportunity to receive dose 3 as BNT162b2 10 mcg in Open Label Period in Troponin group and were followed up to 1 month after dose 3.

Reporting group title	Ph1:5-<12Y:D1-6M After D2/BNT162b2 10 mcg

Reporting group description:

Phase 1: Participants aged 5 to <12 years received dose 1 of BNT162b2 10 mcg intramuscularly and were followed up to 6 month after dose 2.

Reporting group title	Ph1:5-<12Y:D1-6M After D2/BNT162b2 10 mcg

Reporting group description:

Phase 1: Participants aged 5 to <12 years received dose 1 of BNT162b2 10 mcg intramuscularly and were followed up to 6 month after dose 2.

Reporting group title	Ph1:5-<12Y:D1-1M After D2/BNT162b2 (30/30 mcg)

Reporting group description:

Phase 1: Participants aged 5 to <12 years of age received dose 1 of 30 mcg BNT162b2 and received third dose of 10 mcg BNT162b2 were followed up to 1 month after dose 2.

Reporting group title	Ph1:5-<12Y:D1-1M After D2/BNT162b2 (30/10 mcg)

Reporting group description:

Phase 1: Participants aged 5 to <12 years of age received dose 1 of 30 mcg, followed by dose 2 of 10 mcg BNT162b2 and received third dose of 10 mcg BNT162b2 were followed up to 1 month after dose 2.

Reporting group title	Ph1:5-<12Y:D3-1M After D3/BNT162b2 10 mcg

Reporting group description:

Phase 1: Participants aged 5 to <12 years received dose 3 of BNT162b2 10 mcg intramuscularly and were followed up to 1 month after dose 3.

Reporting group title	Ph2/3:Bl PCFup:6M-<2Y:D1-1M After D2/Placebo

Reporting group description:

Phase 2/3:Participants aged 6 months to <2 years were received 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 2.

Reporting group title	Ph2/3:BlPCFup:5 -<12Y:D1-1M After D2 or PTD3/BNT162b2 10 mcg

Reporting group description:

Phase 2/3:Participants aged 5 to <12 years received dose 1 of BNT162b2 10 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 2 or prior to dose 3.

Reporting group title	Ph2/3:Bl OLP:5-<12Y:D3-6M After D3/Org BNT162b2 10 mcg

Reporting group description:

Participants aged 5 to <12 years received dose 3 as Original (Org) BNT162b2 10 mcg in Blinded and Open Label Period were followed up to 6 month after dose 3.

Reporting group title	Ph2/3:Bl PCFup:5-<12Y:TPG:D1-1M After D2/Pb BNT162b2 10 mcg

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) intramuscularly in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 2.

Reporting group title	Ph2/3:Bl OLP:5-<12Y:D3-6M After D3/BNT162b2 10 mcg

Reporting group description:

Participants aged 5 to <12 years were randomised to receive dose 3 as BNT162b2 10 mcg in Blinded

and Open Label Period and were followed up to 6 month after dose 3.

Reporting group title	Ph2/3:Bl OLP:5-<12Y:TPG:D3-1M After D3/Org BNT162b2 10 mcg

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) intramuscularly in Blinded and Open Label period and had the opportunity to receive dose 3 as BNT162b2 10 mcg in Open Label Period in Troponin group and were followed up to 6 month after dose 3.

Serious adverse events	Ph2/3:BlPCFup:6M-<2Y:D1-6M After D2or Prior D3/BNT162b2 3mcg	Ph2/3:Bl PCFup:6 M-<2Y:D1-1M After D2/BNT162b2 3 mcg	Ph2/3:Bl PCFup:6 M-<2Y:D1-1M After D2/Pb
Total subjects affected by serious adverse events			
subjects affected / exposed	24 / 1458 (1.65%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 1458 (0.07%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Ovarian cyst			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular appendage torsion			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	1 / 1458 (0.07%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphyseal fracture			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			

subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			

subjects affected / exposed	1 / 1458 (0.07%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcolepsy			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 1458 (0.07%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Pain in extremity			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	1 / 1458 (0.07%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	3 / 1458 (0.21%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Complicated appendicitis			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	1 / 1458 (0.07%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	1 / 1458 (0.07%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	3 / 1458 (0.21%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	1 / 1458 (0.07%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	2 / 1458 (0.14%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HCoV-NL63 infection			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	1 / 1458 (0.07%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 1458 (0.07%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	1 / 1458 (0.07%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	1 / 1458 (0.07%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	1 / 1458 (0.07%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			

subjects affected / exposed	1 / 1458 (0.07%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 1458 (0.14%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	5 / 1458 (0.34%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 1458 (0.07%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	1 / 1458 (0.07%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ph2/3:Bl PCFup:6M-<2Y:D3-6M After D3/Pb	Ph2/3:Bl PCFup:6M-<2Y:D3-6M After D3/BNT162b2 3mcg	Ph2/3:Bl PCFup:6M-<2Y:D3-1M After D3/Pb
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 237 (0.00%)	1 / 483 (0.21%)	0 / 237 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			

subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular appendage torsion			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			

subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Epiphyseal fracture			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			

subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcolepsy			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			

subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			

subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HCoV-NL63 infection			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			

subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 237 (0.00%)	1 / 483 (0.21%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			

subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ph2/3:Bl PCFup:6M-<2Y:D3-1M After D3/BNT162b2 3mcg	Ph2/3:BlPCFup:6M-<2Y:D1-6M After D2 or Prior D3/Pb	Ph2/3:Bl PCFup:5-<12Y:D1-1M After D2/ BNT162b2 10mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 483 (0.00%)	17 / 718 (2.37%)	0 / 3109 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 483 (0.00%)	2 / 718 (0.28%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular appendage torsion			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Accidental overdose			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphyseal fracture			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			

subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcolepsy			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			

subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			

subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 483 (0.00%)	3 / 718 (0.42%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			

subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HCoV-NL63 infection			
subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			

subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			

subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			

subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 483 (0.00%)	1 / 718 (0.14%)	0 / 3109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ph2/3:Bl PCFup:5-<12Y:TPG:D1-6M After D2/BNT162b2 10 mcg	Ph2/3:BlPCFup:5-<12Y:TPG:D1-6MAfterD2 orPriorD3/BNT162b2 10mcg	Ph2/3:Bl PCFup:2-<5Y:D3-6M After D3/Pb
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 518 (0.00%)	1 / 518 (0.19%)	0 / 405 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular appendage torsion			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 518 (0.00%)	1 / 518 (0.19%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			

subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphyseal fracture			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fall			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			

subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcolepsy			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Pain in extremity			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Complicated appendicitis			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HCoV-NL63 infection			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			

subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ph2/3:Bl PCFup:2-<5Y:D3-6M After D3/BNT162b2 3mcg	Ph2/3:Bl PCFup:2-<5Y:D3-1M After D3/Pb	Ph2/3:Bl PCFup:2-<5Y:D3-1M After D3/BNT162b2 3mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 863 (0.35%)	0 / 405 (0.00%)	0 / 863 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			

subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular appendage torsion			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			

subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Epiphyseal fracture			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			

subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcolepsy			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	1 / 863 (0.12%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	1 / 863 (0.12%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			

subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			

subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HCoV-NL63 infection			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			

subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 863 (0.12%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			

subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ph2/3:BlPCFup:2-<5Y:D1-6M After D2 or Prior D3/Pb	Ph2/3:BlPCFup:2-<5Y:D1-6M After D2 or Prior D3/BNT162b2 3mcg	Ph2/3:Bl PCFup:5-<12Y:TPG:D1-6M After D2 or Prior D3/Pb
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 1173 (0.85%)	11 / 2368 (0.46%)	0 / 260 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 1173 (0.00%)	1 / 2368 (0.04%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular appendage torsion			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	1 / 1173 (0.09%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Accidental overdose			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphyseal fracture			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	1 / 1173 (0.09%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			

subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	1 / 1173 (0.09%)	1 / 2368 (0.04%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	1 / 1173 (0.09%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcolepsy			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			

subjects affected / exposed	0 / 1173 (0.00%)	1 / 2368 (0.04%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Papilloedema			
subjects affected / exposed	1 / 1173 (0.09%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 1173 (0.00%)	1 / 2368 (0.04%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation			
subjects affected / exposed	1 / 1173 (0.09%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 1173 (0.00%)	1 / 2368 (0.04%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			

subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 1173 (0.00%)	2 / 2368 (0.08%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	1 / 1173 (0.09%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			

subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 1173 (0.00%)	1 / 2368 (0.04%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 1173 (0.09%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	1 / 1173 (0.09%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	1 / 1173 (0.09%)	1 / 2368 (0.04%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 1173 (0.00%)	1 / 2368 (0.04%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HCoV-NL63 infection			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			

subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	1 / 1173 (0.09%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 1173 (0.00%)	1 / 2368 (0.04%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			

subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	1 / 1173 (0.09%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1173 (0.00%)	1 / 2368 (0.04%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 1173 (0.00%)	2 / 2368 (0.08%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			

subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ph2/3:BlPCFup:2-<5Y:D1-1M After D2/ BNT162b2 3mcg	Ph2/3:Bl PCFup:2-<5Y:D1-1M After D2/Pb	Ph2/3:5-<12Y:TPG:D3-1M After D3/BNT162b2 10 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast			

disorders			
Ovarian cyst			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular appendage torsion			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphyseal fracture			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			

subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			

subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcolepsy			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Pain in extremity			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Complicated appendicitis			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HCoV-NL63 infection			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			

subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ph2/3:5-<12Y:TPG:D3-1M After D3/BNT162b2 10 mcg	Ph2/3:Bl OLP:5-<12Y:TPG:D3-6M After D3/BNT162b2 10 mcg	Ph1:2-<5Y:D1-1M After D2/BNT162b2 3 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 418 (0.00%)	2 / 418 (0.48%)	0 / 16 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

Pyrexia			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular appendage torsion			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			

subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 418 (0.00%)	1 / 418 (0.24%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Epiphyseal fracture			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			

subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcolepsy			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 418 (0.00%)	1 / 418 (0.24%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			

subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			

subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HCoV-NL63 infection			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			

subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			

subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ph1:6M-<2Y:D3-1M After D3/BNT162b2 3 mcg	Ph1:6M-<2Y:D1-6M After D2/BNT162b2 3 mcg	Ph2/3:OLP:12-<16Y:TPG:D3-1M After D3/BNT162b2 30 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular appendage torsion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Accidental overdose			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphyseal fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcolepsy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HCoV-NL63 infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ph2/3:OLP:12-<16Y:TPG:D1-6M After D2or priorD3/BNT162b2 30mcg	Ph2/3:OLP:12-<16Y:TPG:D1-1M After D2/BNT162b2 30 mcg	Ph1:2-<5Y:D1-1M After D2/BNT162b2 10 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 487 (0.41%)	0 / 487 (0.00%)	0 / 32 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 487 (0.21%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	1 / 487 (0.21%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular appendage torsion			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			

subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphyseal fracture			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fall			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			

subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcolepsy			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Pain in extremity			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Complicated appendicitis			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HCoV-NL63 infection			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			

subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ph1:2-<5Y:D3-1M After D3/BNT162b2 3 mcg	Ph2/3:BlPCFup:5 - <12Y:D1-1M After D2 or PTD3/Pb	Ph2/3:BlOLP:5-<12Y:D3-1M After D3/BNT162b2 10 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 27 (0.00%)	3 / 1538 (0.20%)	0 / 2410 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

Pyrexia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular appendage torsion			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			

subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Epiphyseal fracture			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			

subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcolepsy			
subjects affected / exposed	0 / 27 (0.00%)	1 / 1538 (0.07%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 27 (0.00%)	1 / 1538 (0.07%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 27 (0.00%)	1 / 1538 (0.07%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			

subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	0 / 27 (0.00%)	1 / 1538 (0.07%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			

subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HCoV-NL63 infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			

subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			

subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ph2/3:BlOLP:5-<12Y:D3-1M After D3/BNT162b2 10 mcg	Ph1:5-<12Y:D1-6M After D2/BNT162b2 10 mcg	Ph1:5-<12Y:D1-6M After D2/BNT162b2 10 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular appendage torsion			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Accidental overdose			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphyseal fracture			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			

subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcolepsy			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			

subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			

subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			

subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HCoV-NL63 infection			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			

subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			

subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			

subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ph1:5-<12Y:D1-1M After D2/BNT162b2 (30/30 mcg)	Ph1:5-<12Y:D1-1M After D2/BNT162b2 (30/10 mcg)	Ph1:5-<12Y:D3-1M After D3/BNT162b2 10 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Ovarian cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular appendage torsion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphyseal fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			

subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			

subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcolepsy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Complicated appendicitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HCoV-NL63 infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ph2/3:Bl PCFup:6M-<2Y:D1-1M After D2/Placebo	Ph2/3:BlPCFup:5 -<12Y:D1-1M After D2 or PTD3/BNT162b2 10 mcg	Ph2/3:Bl OLP:5-<12Y:D3-6M After D3/Org BNT162b2 10 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1538 (0.00%)	8 / 3109 (0.26%)	3 / 957 (0.31%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

Pyrexia			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular appendage torsion			
subjects affected / exposed	0 / 1538 (0.00%)	1 / 3109 (0.03%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			

subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Epiphyseal fracture			
subjects affected / exposed	0 / 1538 (0.00%)	1 / 3109 (0.03%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			
subjects affected / exposed	0 / 1538 (0.00%)	1 / 3109 (0.03%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			

subjects affected / exposed	0 / 1538 (0.00%)	1 / 3109 (0.03%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcolepsy			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 1538 (0.00%)	1 / 3109 (0.03%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	1 / 957 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			

subjects affected / exposed	0 / 1538 (0.00%)	1 / 3109 (0.03%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 1538 (0.00%)	1 / 3109 (0.03%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			

subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HCoV-NL63 infection			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			

subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 1538 (0.00%)	1 / 3109 (0.03%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			

subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ph2/3:Bl PCFup:5-<12Y:TPG:D1-1M After D2/Pb BNT162b2 10 mcg	Ph2/3:Bl OLP:5-<12Y:D3-6M After D3/BNT162b2 10 mcg	Ph2/3:Bl OLP:5-<12Y:TPG:D3-1M After D3/Org BNT162b2 10 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 260 (0.00%)	10 / 2410 (0.41%)	0 / 202 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Cyanosis			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 260 (0.00%)	1 / 2410 (0.04%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular appendage torsion			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 260 (0.00%)	1 / 2410 (0.04%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumomediastinum			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 260 (0.00%)	1 / 2410 (0.04%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 260 (0.00%)	1 / 2410 (0.04%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Accidental overdose			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphyseal fracture			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 260 (0.00%)	1 / 2410 (0.04%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 260 (0.00%)	1 / 2410 (0.04%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			

subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcolepsy			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 260 (0.00%)	1 / 2410 (0.04%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			

subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 260 (0.00%)	1 / 2410 (0.04%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 260 (0.00%)	1 / 2410 (0.04%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			

subjects affected / exposed	0 / 260 (0.00%)	1 / 2410 (0.04%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 260 (0.00%)	1 / 2410 (0.04%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovirus infection			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			

subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HCoV-NL63 infection			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			

subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			

subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding intolerance			

subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Ph2/3:BlPCFup:6M-<2Y:D1-6M After D2or Prior D3/BNT162b2 3mcg	Ph2/3:Bl PCFup:6 M-<2Y:D1-1M After D2/BNT162b2 3 mcg	Ph2/3:Bl PCFup:6 M-<2Y:D1-1M After D2/Pb
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1458 (0.00%)	1154 / 1458 (79.15%)	550 / 718 (76.60%)
General disorders and administration site conditions			
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			

subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1458 (0.00%)	237 / 1458 (16.26%)	83 / 718 (11.56%)
occurrences (all)	0	285	96
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Injection site swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1458 (0.00%)	94 / 1458 (6.45%)	26 / 718 (3.62%)
occurrences (all)	0	108	28
Injection site pain (TENDERNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1458 (0.00%)	353 / 1458 (24.21%)	126 / 718 (17.55%)
occurrences (all)	0	448	151
Pyrexia			
subjects affected / exposed	0 / 1458 (0.00%)	43 / 1458 (2.95%)	14 / 718 (1.95%)
occurrences (all)	0	45	14
Malaise			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1458 (0.00%)	184 / 1458 (12.62%)	87 / 718 (12.12%)
occurrences (all)	0	205	96

Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Menarche			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	0 / 1458 (0.00%)	20 / 1458 (1.37%)	5 / 718 (0.70%)
occurrences (all)	0	21	5
Cough			
subjects affected / exposed	0 / 1458 (0.00%)	15 / 1458 (1.03%)	5 / 718 (0.70%)
occurrences (all)	0	18	5
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 1458 (0.00%)	15 / 1458 (1.03%)	6 / 718 (0.84%)
occurrences (all)	0	16	7
Anxiety			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1458 (0.00%)	932 / 1458 (63.92%)	431 / 718 (60.03%)
occurrences (all)	0	1343	615
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			

subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Foreign body ingestion			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1458 (0.00%)	560 / 1458 (38.41%)	274 / 718 (38.16%)
occurrences (all)	0	713	354

Speech disorder developmental			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 1458 (0.00%)	31 / 1458 (2.13%)	17 / 718 (2.37%)
occurrences (all)	0	31	17
Teething			
subjects affected / exposed	0 / 1458 (0.00%)	18 / 1458 (1.23%)	7 / 718 (0.97%)
occurrences (all)	0	18	7
Nausea			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 1458 (0.00%)	27 / 1458 (1.85%)	15 / 718 (2.09%)
occurrences (all)	0	29	17
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

Dermatitis diaper			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 1458 (0.00%)	10 / 1458 (0.69%)	8 / 718 (1.11%)
occurrences (all)	0	10	8
Enterobiasis			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 1458 (0.00%)	16 / 1458 (1.10%)	11 / 718 (1.53%)
occurrences (all)	0	16	11
Periorbital cellulitis			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 1458 (0.00%)	0 / 1458 (0.00%)	0 / 718 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1458 (0.00%)	511 / 1458 (35.05%)	236 / 718 (32.87%)
occurrences (all)	0	619	279

Non-serious adverse events	Ph2/3:Bl PCFup:6M-<2Y:D3-6M After D3/Pb	Ph2/3:Bl PCFup:6M-<2Y:D3-6M After D3/BNT162b2 3mcg	Ph2/3:Bl PCFup:6M-<2Y:D3-1M After D3/Pb
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	119 / 237 (50.21%)
General disorders and administration site conditions			
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	11 / 237 (4.64%)
occurrences (all)	0	0	11
Injection site pain (PAIN)			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Injection site swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	5 / 237 (2.11%)
occurrences (all)	0	0	5
Injection site pain (TENDERNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	22 / 237 (9.28%)
occurrences (all)	0	0	22
Pyrexia			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	2 / 237 (0.84%)
occurrences (all)	0	0	2
Malaise			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	13 / 237 (5.49%)
occurrences (all)	0	0	13
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Menarche			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal			

disorders			
Rhinorrhoea			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	82 / 237 (34.60%)
occurrences (all)	0	0	82
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Foreign body ingestion			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Fall			

subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	27 / 237 (11.39%)
occurrences (all)	0	0	27
Speech disorder developmental			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	7 / 237 (2.95%)
occurrences (all)	0	0	7
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Rash macular			

subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			

subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	4 / 237 (1.69%)
occurrences (all)	0	0	4
Upper respiratory tract infection			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 237 (0.00%)	0 / 483 (0.00%)	29 / 237 (12.24%)
occurrences (all)	0	0	29

Non-serious adverse events	Ph2/3:Bl PCFup:6M-<2Y:D3-1M After D3/BNT162b2 3mcg	Ph2/3:BlPCFup:6M-<2Y:D1-6M After D2 or Prior D3/Pb	Ph2/3:Bl PCFup:5-<12Y:D1-1M After D2/ BNT162b2 10mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	267 / 483 (55.28%)	0 / 718 (0.00%)	2821 / 3109 (90.74%)
General disorders and administration site conditions			
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	413 / 3109 (13.28%)
occurrences (all)	0	0	475
Axillary pain			

subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	1614 / 3109 (51.91%)
occurrences (all)	0	0	2267
Fatigue			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	33 / 483 (6.83%)	0 / 718 (0.00%)	806 / 3109 (25.92%)
occurrences (all)	33	0	1009
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	2603 / 3109 (83.72%)
occurrences (all)	0	0	4439
Injection site pain			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Injection site swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	15 / 483 (3.11%)	0 / 718 (0.00%)	622 / 3109 (20.01%)
occurrences (all)	15	0	770
Injection site pain (TENDERNESS)			

alternative assessment type: Systematic			
subjects affected / exposed	67 / 483 (13.87%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	67	0	0
Pyrexia			
subjects affected / exposed	12 / 483 (2.48%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	13	0	0
Malaise			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	28 / 483 (5.80%)	0 / 718 (0.00%)	243 / 3109 (7.82%)
occurrences (all)	28	0	257
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Menarche			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0

Anxiety			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	191 / 483 (39.54%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	191	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Foreign body ingestion			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0

Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	1193 / 3109 (38.37%)
occurrences (all)	0	0	1573
Presyncope			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	98 / 483 (20.29%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	98	0	0
Speech disorder developmental			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	320 / 3109 (10.29%)
occurrences (all)	0	0	364
Diarrhoea			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Nausea			

subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	6 / 483 (1.24%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	6	0	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	122 / 3109 (3.92%)
occurrences (all)	0	0	125
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Arthralgia (JOINT PAIN)			

alternative assessment type: Systematic			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	235 / 3109 (7.56%)
occurrences (all)	0	0	265
Myalgia			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	561 / 3109 (18.04%)
occurrences (all)	0	0	657
Neck pain			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	4 / 483 (0.83%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	4	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0

Rhinitis			
subjects affected / exposed	0 / 483 (0.00%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	89 / 483 (18.43%)	0 / 718 (0.00%)	0 / 3109 (0.00%)
occurrences (all)	89	0	0

Non-serious adverse events	Ph2/3:Bl PCFup:5-<12Y:TPG:D1-6M After D2/BNT162b2 10 mcg	Ph2/3:BlPCFup:5-<12Y:TPG:D1-6MAfterD2 orPriorD3/BNT162b2 10mcg	Ph2/3:Bl PCFup:2-<5Y:D3-6M After D3/Pb
Total subjects affected by non-serious adverse events			
subjects affected / exposed	442 / 518 (85.33%)	0 / 518 (0.00%)	0 / 405 (0.00%)
General disorders and administration site conditions			
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	50 / 518 (9.65%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	54	0	0
Axillary pain			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	221 / 518 (42.66%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	256	0	0
Fatigue			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			

subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	92 / 518 (17.76%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	107	0	0
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	397 / 518 (76.64%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	522	0	0
Injection site pain			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Injection site swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	69 / 518 (13.32%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	77	0	0
Injection site pain (TENDERNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	16 / 518 (3.09%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	16	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0

Social circumstances			
Menarche			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0

Concussion			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Foreign body ingestion			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	163 / 518 (31.47%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	185	0	0
Presyncope			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Speech disorder developmental			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			

subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	40 / 518 (7.72%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	46	0	0
Diarrhoea			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	13 / 518 (2.51%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	14	0	0
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0

Pruritus			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	35 / 518 (6.76%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	39	0	0
Myalgia			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	81 / 518 (15.64%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	92	0	0
Neck pain			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

COVID-19			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	4 / 518 (0.77%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	4	0	0
Rhinitis			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 518 (0.00%)	0 / 518 (0.00%)	0 / 405 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Ph2/3:Bl PCFup:2-<5Y:D3-6M After D3/BNT162b2 3mcg	Ph2/3:Bl PCFup:2-<5Y:D3-1M After D3/Pb	Ph2/3:Bl PCFup:2-<5Y:D3-1M After D3/BNT162b2 3mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 863 (0.00%)	152 / 405 (37.53%)	398 / 863 (46.12%)
General disorders and administration site conditions			

Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 863 (0.00%)	10 / 405 (2.47%)	22 / 863 (2.55%)
occurrences (all)	0	10	22
Axillary pain			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 863 (0.00%)	91 / 405 (22.47%)	202 / 863 (23.41%)
occurrences (all)	0	91	202
Fatigue			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 863 (0.00%)	18 / 405 (4.44%)	83 / 863 (9.62%)
occurrences (all)	0	18	83
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 863 (0.00%)	48 / 405 (11.85%)	222 / 863 (25.72%)
occurrences (all)	0	48	222
Injection site pain			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Injection site swelling (SWELLING)			

alternative assessment type: Systematic			
subjects affected / exposed	0 / 863 (0.00%)	6 / 405 (1.48%)	25 / 863 (2.90%)
occurrences (all)	0	6	25
Injection site pain (TENDERNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 863 (0.00%)	6 / 405 (1.48%)	11 / 863 (1.27%)
occurrences (all)	0	6	11
Malaise			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 863 (0.00%)	21 / 405 (5.19%)	41 / 863 (4.75%)
occurrences (all)	0	21	41
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Menarche			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Cough			

subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Foreign body ingestion			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Skin laceration			

subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 863 (0.00%)	15 / 405 (3.70%)	36 / 863 (4.17%)
occurrences (all)	0	15	36
Presyncope			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Speech disorder developmental			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 863 (0.00%)	21 / 405 (5.19%)	39 / 863 (4.52%)
occurrences (all)	0	21	39
Diarrhoea			

subjects affected / exposed	0 / 863 (0.00%)	5 / 405 (1.23%)	1 / 863 (0.12%)
occurrences (all)	0	5	1
Teething			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 863 (0.00%)	7 / 405 (1.73%)	2 / 863 (0.23%)
occurrences (all)	0	7	2
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 863 (0.00%)	16 / 405 (3.95%)	16 / 863 (1.85%)
occurrences (all)	0	16	16
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 863 (0.00%)	4 / 405 (0.99%)	9 / 863 (1.04%)
occurrences (all)	0	4	9
Myalgia			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 863 (0.00%)	6 / 405 (1.48%)	15 / 863 (1.74%)
occurrences (all)	0	6	15
Neck pain			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0

Otitis media			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 863 (0.00%)	0 / 405 (0.00%)	0 / 863 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Ph2/3:BlPCFup:2-<5Y:D1-6M After D2 or Prior D3/Pb	Ph2/3:BlPCFup:2-<5Y:D1-6M After D2 or Prior D3/BNT162b2 3mcg	Ph2/3:Bl PCFup:5-<12Y:TPG:D1-6M After D2 or Prior D3/Pb
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
General disorders and administration site conditions			
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			

subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Injection site swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Injection site pain (TENDERNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Menarche			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0

Arthropod bite			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Foreign body ingestion			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0

Speech disorder developmental			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

Dermatitis diaper			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1173 (0.00%)	0 / 2368 (0.00%)	0 / 260 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Ph2/3:BlPCFup:2-<5Y:D1-1M After D2/ BNT162b2 3mcg	Ph2/3:Bl PCFup:2-<5Y:D1-1M After D2/Pb	Ph2/3:5-<12Y:TPG:D3-1M After D3/BNT162b2 10 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1661 / 2368 (70.14%)	778 / 1173 (66.33%)	22 / 202 (10.89%)
General disorders and administration site conditions			
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	125 / 2368 (5.28%)	59 / 1173 (5.03%)	0 / 202 (0.00%)
occurrences (all)	129	63	0
Axillary pain			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	977 / 2368 (41.26%)	487 / 1173 (41.52%)	0 / 202 (0.00%)
occurrences (all)	1247	622	0
Fatigue			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	3 / 202 (1.49%)
occurrences (all)	0	0	3
Injection site bruising			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	379 / 2368 (16.01%)	136 / 1173 (11.59%)	0 / 202 (0.00%)
occurrences (all)	444	154	0
Injection site pain (PAIN)			
alternative assessment type: Systematic			

subjects affected / exposed	998 / 2368 (42.15%)	357 / 1173 (30.43%)	0 / 202 (0.00%)
occurrences (all)	1329	449	0
Injection site pain			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	17 / 202 (8.42%)
occurrences (all)	0	0	18
Injection site swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	182 / 2368 (7.69%)	53 / 1173 (4.52%)	0 / 202 (0.00%)
occurrences (all)	209	57	0
Injection site pain (TENDERNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	37 / 2368 (1.56%)	23 / 1173 (1.96%)	4 / 202 (1.98%)
occurrences (all)	37	24	4
Malaise			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	224 / 2368 (9.46%)	121 / 1173 (10.32%)	0 / 202 (0.00%)
occurrences (all)	237	126	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Menarche			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0

Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	22 / 2368 (0.93%)	14 / 1173 (1.19%)	0 / 202 (0.00%)
occurrences (all)	22	14	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Foreign body ingestion			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Fall			

subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	191 / 2368 (8.07%)	86 / 1173 (7.33%)	0 / 202 (0.00%)
occurrences (all)	211	99	0
Presyncope			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Speech disorder developmental			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	305 / 2368 (12.88%)	160 / 1173 (13.64%)	0 / 202 (0.00%)
occurrences (all)	338	179	0
Diarrhoea			
subjects affected / exposed	22 / 2368 (0.93%)	13 / 1173 (1.11%)	0 / 202 (0.00%)
occurrences (all)	24	13	0
Teething			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	41 / 2368 (1.73%)	13 / 1173 (1.11%)	0 / 202 (0.00%)
occurrences (all)	42	13	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	144 / 2368 (6.08%)	68 / 1173 (5.80%)	0 / 202 (0.00%)
occurrences (all)	150	69	0
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0

Rash macular			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	53 / 2368 (2.24%)	30 / 1173 (2.56%)	0 / 202 (0.00%)
occurrences (all)	53	33	0
Myalgia			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	106 / 2368 (4.48%)	50 / 1173 (4.26%)	0 / 202 (0.00%)
occurrences (all)	114	54	0
Neck pain			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	2 / 202 (0.99%)
occurrences (all)	0	0	2
Ear infection			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			

subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	14 / 2368 (0.59%)	12 / 1173 (1.02%)	0 / 202 (0.00%)
occurrences (all)	14	12	0
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 2368 (0.00%)	0 / 1173 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Ph2/3:5-<12Y:TPG:D3-1M After D3/BNT162b2 10 mcg	Ph2/3:Bl OLP:5-<12Y:TPG:D3-6M After D3/BNT162b2 10 mcg	Ph1:2-<5Y:D1-1M After D2/BNT162b2 3 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	319 / 418 (76.32%)	0 / 418 (0.00%)	10 / 16 (62.50%)
General disorders and administration site conditions			
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	35 / 418 (8.37%)	0 / 418 (0.00%)	1 / 16 (6.25%)
occurrences (all)	35	0	2
Axillary pain			
subjects affected / exposed	5 / 418 (1.20%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	5	0	0

Fatigue (FATIGUE) alternative assessment type: Systematic			
subjects affected / exposed	153 / 418 (36.60%)	0 / 418 (0.00%)	5 / 16 (31.25%)
occurrences (all)	153	0	8
Fatigue			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (REDNESS) alternative assessment type: Systematic			
subjects affected / exposed	67 / 418 (16.03%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	67	0	0
Injection site pain (PAIN) alternative assessment type: Systematic			
subjects affected / exposed	273 / 418 (65.31%)	0 / 418 (0.00%)	7 / 16 (43.75%)
occurrences (all)	273	0	11
Injection site pain			
subjects affected / exposed	7 / 418 (1.67%)	0 / 418 (0.00%)	2 / 16 (12.50%)
occurrences (all)	7	0	2
Injection site swelling (SWELLING) alternative assessment type: Systematic			
subjects affected / exposed	50 / 418 (11.96%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	50	0	0
Injection site pain (TENDERNESS) alternative assessment type: Systematic			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Pyrexia			
subjects affected / exposed	2 / 418 (0.48%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Malaise			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	18 / 418 (4.31%)	0 / 418 (0.00%)	1 / 16 (6.25%)
occurrences (all)	18	0	1
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Menarche			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Arthropod bite			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Contusion			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Concussion			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Foreign body ingestion			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)			
alternative assessment type: Systematic			

subjects affected / exposed	93 / 418 (22.25%)	0 / 418 (0.00%)	2 / 16 (12.50%)
occurrences (all)	93	0	4
Presyncope			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Speech disorder developmental			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	19 / 418 (4.55%)	0 / 418 (0.00%)	1 / 16 (6.25%)
occurrences (all)	19	0	2
Diarrhoea			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Vomiting			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 418 (1.67%)	0 / 418 (0.00%)	1 / 16 (6.25%)
occurrences (all)	7	0	1
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			

subjects affected / exposed	23 / 418 (5.50%)	0 / 418 (0.00%)	1 / 16 (6.25%)
occurrences (all)	23	0	1
Myalgia			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	73 / 418 (17.46%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	73	0	0
Neck pain			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	8 / 418 (1.91%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	8	0	0
Ear infection			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rhinitis			

subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 418 (0.00%)	0 / 418 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Ph1:6M-<2Y:D3-1M After D3/BNT162b2 3 mcg	Ph1:6M-<2Y:D1-6M After D2/BNT162b2 3 mcg	Ph2/3:OLP:12-<16Y:TPG:D3-1M After D3/BNT162b2 30 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 15 (46.67%)	10 / 16 (62.50%)	285 / 433 (65.82%)
General disorders and administration site conditions			
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	52 / 433 (12.01%)
occurrences (all)	0	0	52
Axillary pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	149 / 433 (34.41%)
occurrences (all)	0	0	149
Fatigue			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 15 (13.33%)	3 / 16 (18.75%)	14 / 433 (3.23%)
occurrences (all)	2	3	14
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	257 / 433 (59.35%)
occurrences (all)	0	0	257
Injection site pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Injection site swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 15 (6.67%)	1 / 16 (6.25%)	12 / 433 (2.77%)
occurrences (all)	1	1	12
Injection site pain (TENDERNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 15 (26.67%)	1 / 16 (6.25%)	0 / 433 (0.00%)
occurrences (all)	4	1	0
Pyrexia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 15 (6.67%)	2 / 16 (12.50%)	14 / 433 (3.23%)
occurrences (all)	1	3	14
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0

Social circumstances			
Menarche			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 433 (0.00%)
occurrences (all)	0	2	0
Cough			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 15 (26.67%)	8 / 16 (50.00%)	0 / 433 (0.00%)
occurrences (all)	4	12	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0

Concussion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Foreign body ingestion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	143 / 433 (33.03%)
occurrences (all)	0	0	143
Presyncope			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 15 (6.67%)	4 / 16 (25.00%)	0 / 433 (0.00%)
occurrences (all)	1	5	0
Speech disorder developmental			
subjects affected / exposed	1 / 15 (6.67%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			

subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	18 / 433 (4.16%)
occurrences (all)	0	0	18
Diarrhoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	11 / 433 (2.54%)
occurrences (all)	0	0	11
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0

Pruritus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 15 (0.00%)	1 / 16 (6.25%)	0 / 433 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	26 / 433 (6.00%)
occurrences (all)	0	0	26
Myalgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	76 / 433 (17.55%)
occurrences (all)	0	0	76
Neck pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

COVID-19			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 16 (0.00%)	0 / 433 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 15 (13.33%)	2 / 16 (12.50%)	0 / 433 (0.00%)
occurrences (all)	2	3	0

Non-serious adverse events	Ph2/3:OLP:12-<16Y:TPG:D1-6M After D2or priorD3/BNT162b2 30mcg	Ph2/3:OLP:12-<16Y:TPG:D1-1M After D2/BNT162b2 30 mcg	Ph1:2-<5Y:D1-1M After D2/BNT162b2 10 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 487 (0.00%)	414 / 487 (85.01%)	32 / 32 (100.00%)
General disorders and administration site conditions			

Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 487 (0.00%)	88 / 487 (18.07%)	3 / 32 (9.38%)
occurrences (all)	0	104	4
Axillary pain			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 487 (0.00%)	255 / 487 (52.36%)	23 / 32 (71.88%)
occurrences (all)	0	364	34
Fatigue			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Injection site discomfort			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 487 (0.00%)	12 / 487 (2.46%)	9 / 32 (28.13%)
occurrences (all)	0	14	14
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 487 (0.00%)	384 / 487 (78.85%)	21 / 32 (65.63%)
occurrences (all)	0	603	37
Injection site pain			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	3 / 32 (9.38%)
occurrences (all)	0	0	3
Injection site swelling (SWELLING)			

alternative assessment type: Systematic			
subjects affected / exposed	0 / 487 (0.00%)	27 / 487 (5.54%)	4 / 32 (12.50%)
occurrences (all)	0	29	4
Injection site pain (TENDERNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 487 (0.00%)	33 / 487 (6.78%)	9 / 32 (28.13%)
occurrences (all)	0	35	12
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Menarche			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Cough			

subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Concussion			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Foreign body ingestion			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Skin laceration			

subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 487 (0.00%)	228 / 487 (46.82%)	8 / 32 (25.00%)
occurrences (all)	0	307	8
Presyncope			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Speech disorder developmental			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	2 / 32 (6.25%)
occurrences (all)	0	0	2
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 487 (0.00%)	66 / 487 (13.55%)	5 / 32 (15.63%)
occurrences (all)	0	75	6
Diarrhoea			

subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 487 (0.00%)	22 / 487 (4.52%)	2 / 32 (6.25%)
occurrences (all)	0	24	3
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Rash macular			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	2
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 487 (0.00%)	69 / 487 (14.17%)	1 / 32 (3.13%)
occurrences (all)	0	80	1
Myalgia			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 487 (0.00%)	167 / 487 (34.29%)	4 / 32 (12.50%)
occurrences (all)	0	213	5
Neck pain			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 487 (0.00%)	6 / 487 (1.23%)	0 / 32 (0.00%)
occurrences (all)	0	6	0
Ear infection			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Otitis media			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 487 (0.00%)	0 / 487 (0.00%)	0 / 32 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Ph1:2-<5Y:D3-1M After D3/BNT162b2 3 mcg	Ph2/3:BlPCFup:5 - <12Y:D1-1M After D2 or PTD3/Pb	Ph2/3:BlOLP:5-<12Y:D3-1M After D3/BNT162b2 10 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 27 (62.96%)	0 / 1538 (0.00%)	1794 / 2410 (74.44%)
General disorders and administration site conditions			
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	231 / 2410 (9.59%)
occurrences (all)	0	0	231
Axillary pain			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 27 (29.63%)	0 / 1538 (0.00%)	897 / 2410 (37.22%)
occurrences (all)	8	0	897
Fatigue			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	14 / 2410 (0.58%)
occurrences (all)	0	0	14
Injection site bruising			

subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 27 (3.70%)	0 / 1538 (0.00%)	354 / 2410 (14.69%)
occurrences (all)	1	0	354
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	9 / 27 (33.33%)	0 / 1538 (0.00%)	1568 / 2410 (65.06%)
occurrences (all)	9	0	1568
Injection site pain			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	34 / 2410 (1.41%)
occurrences (all)	0	0	34
Injection site swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	286 / 2410 (11.87%)
occurrences (all)	0	0	286
Injection site pain (TENDERNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	13 / 2410 (0.54%)
occurrences (all)	0	0	13
Malaise			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			

alternative assessment type: Systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	154 / 2410 (6.39%)
occurrences (all)	0	0	154
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Menarche			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Animal bite			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Foreign body ingestion			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 27 (3.70%)	0 / 1538 (0.00%)	610 / 2410 (25.31%)
occurrences (all)	1	0	610
Presyncope			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Somnolence (DROWSINESS)			

alternative assessment type: Systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Speech disorder developmental			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	40 / 2410 (1.66%)
occurrences (all)	0	0	40
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 27 (3.70%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	1	0	0
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 27 (3.70%)	0 / 1538 (0.00%)	104 / 2410 (4.32%)
occurrences (all)	1	0	104
Diarrhoea			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 27 (3.70%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	2 / 27 (7.41%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	2	0	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	61 / 2410 (2.53%)
occurrences (all)	0	0	61
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	129 / 2410 (5.35%)
occurrences (all)	0	0	129
Myalgia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Myalgia (MUSCLE PAIN)			

alternative assessment type: Systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	350 / 2410 (14.52%)
occurrences (all)	0	0	350
Neck pain			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis			
subjects affected / exposed	1 / 27 (3.70%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	1	0	0
Otitis media			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 27 (0.00%)	0 / 1538 (0.00%)	0 / 2410 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Ph2/3:BlOLP:5-<12Y:D3-1M After D3/BNT162b2 10 mcg	Ph1:5-<12Y:D1-6M After D2/BNT162b2 10 mcg	Ph1:5-<12Y:D1-6M After D2/BNT162b2 10 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	80 / 957 (8.36%)	16 / 16 (100.00%)	16 / 16 (100.00%)
General disorders and administration site conditions			
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 957 (0.00%)	5 / 16 (31.25%)	7 / 16 (43.75%)
occurrences (all)	0	5	11
Axillary pain			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 957 (0.00%)	14 / 16 (87.50%)	13 / 16 (81.25%)
occurrences (all)	0	19	21
Fatigue			
subjects affected / exposed	16 / 957 (1.67%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	16	0	0
Injection site bruising			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 957 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Injection site erythema			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 957 (0.00%)	8 / 16 (50.00%)	3 / 16 (18.75%)
occurrences (all)	0	8	3

Injection site pain (PAIN) alternative assessment type: Systematic			
subjects affected / exposed	0 / 957 (0.00%)	14 / 16 (87.50%)	15 / 16 (93.75%)
occurrences (all)	0	28	27
Injection site pain			
subjects affected / exposed	60 / 957 (6.27%)	1 / 16 (6.25%)	1 / 16 (6.25%)
occurrences (all)	60	1	1
Injection site swelling (SWELLING) alternative assessment type: Systematic			
subjects affected / exposed	0 / 957 (0.00%)	8 / 16 (50.00%)	3 / 16 (18.75%)
occurrences (all)	0	8	4
Injection site pain (TENDERNESS) alternative assessment type: Systematic			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	10 / 957 (1.04%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	10	0	1
Malaise			
subjects affected / exposed	0 / 957 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Pyrexia (FEVER) alternative assessment type: Systematic			
subjects affected / exposed	0 / 957 (0.00%)	3 / 16 (18.75%)	4 / 16 (25.00%)
occurrences (all)	0	3	4
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 957 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Social circumstances			
Menarche			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			

Dysmenorrhoea			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Foreign body ingestion			

subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 957 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Fracture			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 957 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 957 (0.00%)	10 / 16 (62.50%)	11 / 16 (68.75%)
occurrences (all)	0	12	14
Presyncope			
subjects affected / exposed	0 / 957 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Speech disorder developmental			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	7 / 957 (0.73%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	7	0	2
Gastrointestinal disorders			
Abdominal discomfort			

subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 957 (0.00%)	1 / 16 (6.25%)	1 / 16 (6.25%)
occurrences (all)	0	2	1
Diarrhoea			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 957 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Rash			

subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 957 (0.00%)	1 / 16 (6.25%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Costochondritis			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 957 (0.00%)	1 / 16 (6.25%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Myalgia			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 957 (0.00%)	2 / 16 (12.50%)	5 / 16 (31.25%)
occurrences (all)	0	2	7
Neck pain			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ear infection			

subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 957 (0.00%)	0 / 16 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Ph1:5-<12Y:D1-1M After D2/BNT162b2 (30/30 mcg)	Ph1:5-<12Y:D1-1M After D2/BNT162b2 (30/10 mcg)	Ph1:5-<12Y:D3-1M After D3/BNT162b2 10 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	11 / 12 (91.67%)	35 / 38 (92.11%)
General disorders and administration site conditions			
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 4 (75.00%)	5 / 12 (41.67%)	6 / 38 (15.79%)
occurrences (all)	5	6	6
Axillary pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 4 (100.00%)	10 / 12 (83.33%)	15 / 38 (39.47%)
occurrences (all)	8	15	15
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Injection site bruising			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 4 (0.00%)	1 / 12 (8.33%)	1 / 38 (2.63%)
occurrences (all)	0	1	1
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 4 (100.00%)	3 / 12 (25.00%)	11 / 38 (28.95%)
occurrences (all)	7	4	11
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 4 (100.00%)	11 / 12 (91.67%)	33 / 38 (86.84%)
occurrences (all)	8	21	33
Injection site pain			
subjects affected / exposed	0 / 4 (0.00%)	2 / 12 (16.67%)	1 / 38 (2.63%)
occurrences (all)	0	2	1
Injection site swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 4 (75.00%)	1 / 12 (8.33%)	5 / 38 (13.16%)
occurrences (all)	4	1	5
Injection site pain (TENDERNESS)			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 4 (100.00%)	4 / 12 (33.33%)	1 / 38 (2.63%)
occurrences (all)	4	4	1
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Menarche			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Anxiety			

subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Foreign body ingestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Skin laceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)			

alternative assessment type: Systematic			
subjects affected / exposed	3 / 4 (75.00%)	6 / 12 (50.00%)	13 / 38 (34.21%)
occurrences (all)	6	8	13
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Speech disorder developmental			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 4 (25.00%)	0 / 12 (0.00%)	1 / 38 (2.63%)
occurrences (all)	1	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 4 (50.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	2	0	0
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Nausea			

subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	1 / 12 (8.33%)	0 / 38 (0.00%)
occurrences (all)	0	1	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 4 (25.00%)	2 / 12 (16.67%)	1 / 38 (2.63%)
occurrences (all)	1	2	1
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	1 / 38 (2.63%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	1	0	0
Costochondritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Arthralgia (JOINT PAIN)			

alternative assessment type: Systematic			
subjects affected / exposed	1 / 4 (25.00%)	1 / 12 (8.33%)	1 / 38 (2.63%)
occurrences (all)	2	1	1
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 4 (100.00%)	1 / 12 (8.33%)	3 / 38 (7.89%)
occurrences (all)	6	1	3
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Rhinitis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 12 (0.00%)	0 / 38 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Ph2/3:Bl PCFup:6M-<2Y:D1-1M After D2/Placebo	Ph2/3:BlPCFup:5 -<12Y:D1-1M After D2 or PTD3/BNT162b2 10 mcg	Ph2/3:Bl OLP:5-<12Y:D3-6M After D3/Org BNT162b2 10 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1083 / 1538 (70.42%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
General disorders and administration site conditions			
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	129 / 1538 (8.39%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	150	0	0
Axillary pain			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	641 / 1538 (41.68%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	879	0	0
Fatigue			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			

subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	148 / 1538 (9.62%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	170	0	0
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	661 / 1538 (42.98%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	916	0	0
Injection site pain			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Injection site swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	78 / 1538 (5.07%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	87	0	0
Injection site pain (TENDERNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	40 / 1538 (2.60%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	42	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0

Social circumstances			
Menarche			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0

Concussion			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Foreign body ingestion			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	506 / 1538 (32.90%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	656	0	0
Presyncope			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Speech disorder developmental			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Lymphadenopathy			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	138 / 1538 (8.97%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	151	0	0
Diarrhoea			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	55 / 1538 (3.58%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	57	0	0
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Erythema			

subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	110 / 1538 (7.15%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	127	0	0
Myalgia			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	192 / 1538 (12.48%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	230	0	0
Neck pain			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0

Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 1538 (0.00%)	0 / 3109 (0.00%)	0 / 957 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Ph2/3:Bl PCFup:5-<12Y:TPG:D1-1M After D2/Pb BNT162b2 10 mcg	Ph2/3:Bl OLP:5-<12Y:D3-6M After D3/BNT162b2 10 mcg	Ph2/3:Bl OLP:5-<12Y:TPG:D3-1M After D3/Org BNT162b2 10 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	163 / 260 (62.69%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
General disorders and administration site conditions			

Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	31 / 260 (11.92%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	33	0	0
Axillary pain			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	105 / 260 (40.38%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	128	0	0
Fatigue			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Injection site erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	17 / 260 (6.54%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	18	0	0
Injection site pain (PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	79 / 260 (30.38%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	98	0	0
Injection site pain			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Injection site swelling (SWELLING)			

alternative assessment type: Systematic			
subjects affected / exposed	14 / 260 (5.38%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	17	0	0
Injection site pain (TENDERNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 260 (3.08%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	8	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Menarche			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinorrhoea			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Cough			

subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Foreign body ingestion			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Skin laceration			

subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	77 / 260 (29.62%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	88	0	0
Presyncope			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Somnolence (DROWSINESS)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Speech disorder developmental			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Diarrhea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	26 / 260 (10.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	27	0	0
Diarrhoea			

subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 260 (3.08%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	9	0	0
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	22 / 260 (8.46%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	25	0	0
Myalgia			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	31 / 260 (11.92%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	38	0	0
Neck pain			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Periorbital cellulitis			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0

Otitis media			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 260 (1.15%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	3	0	0
Rhinitis			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 260 (0.00%)	0 / 2410 (0.00%)	0 / 202 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 September 2019	Amendment 3: Updated to allow an additional 2250 Phase 2/3 selected-dose Participants 5 years of age, to enlarge the size of the pediatric safety database. This has resulted in the total number of participants in this portion of the study increasing to approximately 9000 participants. Included blood draws, procedures, and objectives for potential troponin I testing in participants ≥5 to 12 and ≥12 to 16 years. Added the rationale for collecting serum samples for potential troponin I testing.Revised an objective and corresponding endpoint to describe severe COVID-19 cases in participants in the selected-dose portion of the study. Clarified the process for participants who become eligible for receipt of BNT162b2 or another COVID-19 vaccine prior to Visit 5 (6-month follow-up visit). Added a second definition of symptoms of severe COVID-19 disease per the CDC definition. Clarified instructions on how to unblind participants at the 6-month follow-up visit. Updated information on the recording of nonstudy vaccination and concomitant medications.
05 March 2021	Amendment 1: Added 2 age groups to the study: participants ≥2 to <5 years and ≥6 months to <2 years of age, to also study safety and immunogenicity in these age groups. Updated efficacy objectives to apply across ages in which immunobridging has been successful, if 22 cases are accrued. Made updates to match Pfizer's response to 04 February 2021 CBER comments regarding this study, ie: Exclusion criterion 3 applied to all study participants rather than just to Phase 1 participants. References to "noninferiority" updated to "immunobridging." Made additions to the exclusion criteria for previous or current diagnosis of MIS-C. Added to the exclusion criteria receipt of any passive antibody therapy specific to COVID-19 within 90 days prior to enrollment. Specified that placebo recipients who decline BNT162b2 will be followed for 24 months (Visits X and Y). Temporary delay of study intervention criteria regarding nonstudy vaccination updated to be most permissive, ie, to allow easier scheduling around childhood routine vaccinations. Added the following symptoms as prompts to complete the COVID-19/MIS-C illness e-diary: Inability to eat/poor feeding in participants <5 years of age; Abdominal pain; Hospitalization due to confirmed COVID-19 infection. Following updates made to the first confirmed COVID-19 case definition to accommodate inclusion of participants 5 years of age: Definition of diarrhea added. Inability to eat/poor feeding in participants 5 years of age added as an additional symptom. Definition of SARS-CoV-2–related hospitalization added. RR and HR required to meet the SARS-CoV-2–related severe case definition specified by participant age. Table 4 inserted. Added that cell-mediated immune responses will be described following isolation of PBMCs in a subset of Phase 2/3 participants ≥10 years of age. Corresponding visit (Visit 3) added approximately 7 days after Dose 2.

06 August 2021	Amendment 2: Made the following updates in response to commitments made to CBER concerning myocarditis and pericarditis: Insertion of additional row in risk assessment table in risk assessment section. Addition of myocarditis and pericarditis in Adverse Events of Special Interest section. Addition of a procedure to any visit that occurs sooner than 1 month after any vaccination. Addition of an unplanned visit to capture data pertaining to myocarditis and pericarditis. Revised protocol title to reflect the changes in age and dose evaluation.Updated to allow an additional 2250 Phase 2/3 selected-dose participants to enlarge the size of the pediatric safety database. Added Phase 1/2/3 evaluation of lower dose levels for children and young adults with corresponding objectives. Revised the order of Visit 1 activities to clarify when procedures should be conducted in relation to study intervention administration when the visit occurs over 2 consecutive days. Added updates and reformatted activities in the SoA. Removed the requirement to conduct a potential COVID-19 convalescent visit following each potential COVID-19 illness visit. The collection of the blood sample was to support an exploratory endpoint, which will be addressed with external data and thereby reduce burden to participants and caregivers. Added a country-specific appendix that allows flexibility to conduct scheduled follow-up visits in the participant's home, ie, site-arranged home health visits, as permitted per local guidelines (applicable to Poland only).
29 September 2021	Amendment 4: Revised the success criterion for the efficacy hypotheses to the lower limit of 95% CI 30, in response to regulatory feedback. Added Section 1.1.1, requiring the avoidance of strenuous or endurance exercise 4 days prior to Visit 1 through Visit 1 and from Visit 2 through Visit 3 for the potential troponin I testing subset. Clarified that Phase 2/3 selected-dose participants who originally received active vaccine and are unblinded before Visit 5 will complete the original SoA (Section 1.3.3) before transitioning to the SoA in Section 1.3.3.1.
15 November 2021	Amendment 5: Based on the 10-µg immunobridging data in the ≥5- to 12-year age group, revised Phase 1/2/3 evaluation of lower dose schedules for children and adolescents. Revised age range for the oldest age group. Revised corresponding objectives, estimands, and endpoints. Revised corresponding SoA and procedures. Revised details in the statistical methods sections. Added flexibility for Visit 5 to be conducted as a telephone visit for the 4500 participants included to enlarge the size of the pediatric safety database, reducing the burden on the participant or participant's parent(s)/legal guardian. Included an exploratory objective to describe the immune response to emerging VOCs. Added the instruction that participants who receive COVID-19 vaccines outside of the study from protocol amendment 5 onwards should be withdrawn to maintain the appropriate assessment of the study intervention. Removed the lifestyle consideration related to strenuous or endurance exercise (potential troponin I testing group only) following regulatory feedback. Updated the appendix for SAE reporting to include guidance on how to report SAEs to Pfizer Safety via an electronic data collection tool.

04 January 2022	Amendment 6: The primary immunogenicity analysis demonstrated that the immune response elicited by BNT162b2 in participants ≥2 to 5 years of age (2 doses at 3 µg) did not meet immunobridging criteria when compared to participants 16 to 25 years of age from the C4591001 study. As a result, and given the emerging data in individuals 16 years of age and older, an additional (third) dose of BNT162b2 will be administered to all Phase 1 dose-finding and Phase 2/3 selected-dose participants: Added corresponding objectives, estimands, and endpoints. Added corresponding SoA and procedures. Added details in the statistical methods sections. Cell-mediated immune responses will also be described following isolations of PBMCs in a subset of Phase 2/3 participants who receive a third dose. An additional 4500 Phase 2/3 selected-dose participants ≥6 months to 2 years and ≥2 to 5 years of age are permitted to enroll to enlarge the size of the pediatric safety database. Clarified that participants who decline the opportunity to receive third dose should be withdrawn. Clarified that the interval between the second and third doses will be based on the participant's age at the time of enrollment. Clarified that the dose level of BNT162b2 will be based on age at the time of vaccination. As the asymptomatic efficacy objective is now restricted to participants ≥5 to 12 years of age, in the Phase 2/3 selected-dose portion, participants ≥6 months to 5 years of age who enrolled before protocol amendment 6 will no longer have a blood sample for immunogenicity testing at Visit 5 (6-month follow-up). Time frames for prohibited nonstudy vaccines were simplified. For the option of a 3-µg dose level, an additional unit dose strength was added. For participants 5 years of age, all positive RT-PCR cases confirmed by the central laboratory will undergo BioFire testing.
10 March 2022	Amendment 7: Given the emerging data in individuals 16 years of age and older, an additional (third) dose of BNT162b2 at least 5 months after Dose 2 to all Phase 2/3 participants enrolled to support obtaining serum samples for potential troponin I testing (≥5 to12 years of age, placebo-controlled, and ≥12 to 16 years of age, open-label):Clarified both symptomatic and asymptomatic COVID-19 infection will result in temporary delay of enrollment, randomization, or study intervention administration. Clarified that the dose interval for Phase 2/3 selected-dose participants enrolled in the ≥2 to 5 years age group who originally received placebo and will turn 5 years of age prior to crossing over to active vaccine will be the same as for the ≥5 to 12 years age group (ie, third dose administered at least 6 months after the second dose). Additional clarification for Phase 2/3 selected-dose parents/legal guardians that decline the blinded third dose. Added flexibility to inclusion and exclusion criteria (based on investigator's judgment) for Phase 1 dose-finding participants when receiving Dose 3. Clarified that, for Phase 1 dose-finding participants, height and weight should be collected once at Visit 1 only as part of the physical examination; likewise, the participant's randomization number and study intervention allocation are obtained using the IRT system at Visit 1 only. The timing of cases for these 2 groups are similar, therefore making it more likely to compare cases of the same variant. Added collection of maternal COVID-19 immunization and breastfeeding data for participants who are ≥6 months to 2 years of age in the Phase 2/3 selected-dose portion of the study. Updated the risk assessment to align with the current version of the IB.

28 April 2023	Amendment 8: Updated schedules of assessments and protocol text to identify study visits that no longer need to be completed.Updated study procedures to describe site actions following approval of protocol amendment 8.Removed the lower-dose-evaluation substudy of the protocol. The FDA has approved the request for the lower-dose evaluation postmarketing commitment release in November 2022. Provided further guidance for participants withdrawal from the study for Phase 2/3 selected-dose parents/legal guardians that decline the blinded third dose. Added a statement that participants in Mexico will not self collect nasal swabs per Mexican regulatory request. Clarified that the window for provision of a third dose of BNT162b2 for participants ≥5 years of age to 12 years of age in the US is in line with changing regulatory requirements (emergency use approvals). Removed blood sample collection for immunogenicity testing at certain study visits for Phase 1 dose-finding participants and Phase 2/3 selected-dose participants who are part of the immunogenicity subset to reduce the burden of procedures on participants and caregivers for those enrolling in study C4591048. Secondary/exploratory objectives with corresponding text throughout the protocol removed: To describe the efficacy of prophylactic BNT162b2 against asymptomatic infection in participants ≥5 to 12 years age in the selected-dose portion of the study without evidence of past SARS-CoV-2 infection. To describe the serological responses in Phase 2/3 participants in the selected-dose portion of the study to BNT162b2 at the dose level selected in each age group in cases of: Confirmed COVID-19 with and without coinfection or Confirmed severe COVID-19 or SARS-CoV-2 infection without confirmed COVID-19. Added exploratory objective to describe the incidence of confirmed COVID-19 through the entire study follow-up period. Added corresponding estimands, endpoints, and statistical analysis methods.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported