Clinical trial results:
A multi-site, Phase I/II, 2-part, dose escalation trial investigating the safety and immunogenicity of four prophylactic SARS-CoV-2 RNA vaccines against COVID-19 using different dosing regimens in healthy and immunocompromised adults

Summary

EudraCT number	2020-001038-36
Trial protocol	DE
Global end of trial date	13 April 2022

Results information

Result version number	v2 (current)
This version publication date	24 January 2025
First version publication date	27 April 2023
Version creation reason	• New data added to full data set An explanatory sentence was added to the endpoint "Percentage of Participants With at Least 1 Unsolicited TEAE Occurring After Dose 1 up to 28 Days After Dose 2 Boost Immunization) or After Dose 1 (Prime Immunization) (if no Dose 2)" to explain why not all arms/groups were evaluated.

Trial information

Trial identification

Sponsor protocol code	BNT162-01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04380701
WHO universal trial number (UTN)	U1111-1249-4220

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, 0049 613190840, patients@biontech.de
Scientific contact	BioNTech clinical trials patient information, BioNTech SE, 0049 613190840, patients@biontech.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 September 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 April 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the safety and tolerability profiles of prophylactic BNT162 vaccines in healthy adults after single dose (SD; prime only) or prime/boost (P/B) immunization.

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 Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 April 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 512
Worldwide total number of subjects	512
EEA total number of subjects	512

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)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	434
From 65 to 84 years	78

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study participants were selected from the volunteer panel at the clinical CRO, volunteers who responded to either generic or study-specific advertisements in social media, or volunteers who contacted the clinical CRO via a web-based study participant recruitment portal.

Pre-assignment

Screening details:

Study participants were selected from this pool of volunteers according to inclusion and exclusion criteria. The first participant was enrolled on 23 APR 2020. All enrolled participants were allocated to treatment.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.1 µg

Arm description:

BNT162a1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162a1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular (IM); upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.3 µg

Arm description:

BNT162a1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162a1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162a1 - Part A Participants Aged 18 to 55 Years - 3 µg

Arm description:

BNT162a1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the Safety Review Committee [SRC]).

Arm type	Experimental

Investigational medicinal product name	BNT162a1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. The non-dominant arm was preferred.

Arm title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 1 µg

Arm description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162b1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 3 µg

Arm description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162b1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 10 µg

Arm description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162b1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 20 µg

Arm description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Arm type	Experimental

Investigational medicinal product name	BNT162b1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 30 µg

Arm description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162b1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 50 µg

Arm description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162b1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 60 µg

Arm description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the SRC).

Arm type	Experimental
Investigational medicinal product name	BNT162b1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. The non-dominant arm was preferred.

Arm title	BNT162b1 - Part A Participants Aged 56 to 85 Years - 10 µg

Arm description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Arm type	Experimental

Investigational medicinal product name	BNT162b1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b1 - Part A Participants Aged 56 to 85 Years - 20 µg

Arm description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162b1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b1 - Part A Participants Aged 56 to 85 Years - 30 µg

Arm description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162b1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 1 µg

Arm description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

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

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 3 µg

Arm description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Arm type	Experimental

Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 10 µg

Arm description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

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

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 20 µg

Arm description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

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

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 30 µg

Arm description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

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

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b2 - Part A Participants Aged 56 to 85 Years - 10 µg

Arm description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Arm type	Experimental

Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b2 - Part A Participants Aged 56 to 85 Years - 20 µg

Arm description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

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

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b2 - Part A Participants Aged 56 to 85 Years - 30 µg

Arm description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

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

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg HIV

Arm description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen), Immunocompromised participants (ICP) expansion cohort (Cohort 13).

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

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg PT

Arm description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen), ICP expansion cohort (Cohort 13). PT = post-transplant.

Arm type	Experimental

Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b2 - Part A Participants Aged 18 to 85 Years - 3 & 30 µg

Arm description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen), alternative posology dose group expansion cohort (Cohort 11).

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

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C12

Arm description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen), adaptive immune response dose group expansion cohort (C12 = Cohort 12).

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

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C14

Arm description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen), B-cell immune response dose group expansion cohort (C14 = Cohort 14).

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

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg

Arm description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as

intramuscular injection (P/B regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162c2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg

Arm description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162c2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg

Arm description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162c2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 3 µg

Arm description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162c2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. For the P/B regimens, use of the same arm for both doses was allowed. The non-dominant arm was preferred.

Arm title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg SD

Arm description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (single dose [SD] regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162c2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. The non-dominant arm was preferred.

Arm title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg SD

Arm description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (SD regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162c2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. The non-dominant arm was preferred.

Arm title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.6 µg SD

Arm description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (SD regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162c2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. The non-dominant arm was preferred.

Arm title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg SD

Arm description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (SD regimen).

Arm type	Experimental
Investigational medicinal product name	BNT162c2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

IM; upper arm, musculus deltoideus. The non-dominant arm was preferred.

Number of subjects in period 1	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 3 µg
Started	12	12	6
Completed end of treatment phase	12	12	6
Completed	12	12	6
Not completed	0	0	0
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	-
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Roll-over into trial BNT162-14	-	-	-
Non-trial SARS-COV-2 vaccination due to COVID-19	-	-	-
Pregnancy	-	-	-
Private reason(s)	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	BNT162b1 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 10 µg
Started	12	12	12
Completed end of treatment phase	12	12	11
Completed	12	12	11
Not completed	0	0	1
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	-
Physician decision	-	-	-
Adverse event, non-fatal	-	-	1
Roll-over into trial BNT162-14	-	-	-
Non-trial SARS-COV-2 vaccination due to COVID-19	-	-	-
Pregnancy	-	-	-
Private reason(s)	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	BNT162b1 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 30 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 50 µg
Started	12	12	12
Completed end of treatment phase	10	11	11
Completed	10	11	11
Not completed	2	1	1
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	1	-
Physician decision	-	-	-

Adverse event, non-fatal	-	-	-
Roll-over into trial BNT162-14	-	-	-
Non-trial SARS-COV-2 vaccination due to COVID-19	-	-	-
Pregnancy	-	-	-
Private reason(s)	1	-	1
Lost to follow-up	-	-	-

Number of subjects in period 1	BNT162b1 - Part A Participants Aged 18 to 55 Years - 60 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 20 µg
Started	12	12	12
Completed end of treatment phase	12	12	12
Completed	11	12	11
Not completed	1	0	1
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	1
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Roll-over into trial BNT162-14	-	-	-
Non-trial SARS-COV-2 vaccination due to COVID-19	-	-	-
Pregnancy	-	-	-
Private reason(s)	1	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	BNT162b1 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 3 µg
Started	12	12	12
Completed end of treatment phase	12	11	12
Completed	12	11	12
Not completed	0	1	0
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	1	-
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Roll-over into trial BNT162-14	-	-	-
Non-trial SARS-COV-2 vaccination due to COVID-19	-	-	-
Pregnancy	-	-	-
Private reason(s)	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	BNT162b2 - Part A Participants Aged 18 to 55 Years - 10 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 30 µg

Started	12	12	12
Completed end of treatment phase	11	12	12
Completed	11	11	12
Not completed	1	1	0
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	1	-
Physician decision	-	-	-
Adverse event, non-fatal	1	-	-
Roll-over into trial BNT162-14	-	-	-
Non-trial SARS-COV-2 vaccination due to COVID-19	-	-	-
Pregnancy	-	-	-
Private reason(s)	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	BNT162b2 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 20 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 30 µg
Started	12	12	12
Completed end of treatment phase	12	12	12
Completed	12	11	11
Not completed	0	1	1
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	-
Physician decision	-	-	-
Adverse event, non-fatal	-	1	-
Roll-over into trial BNT162-14	-	-	-
Non-trial SARS-COV-2 vaccination due to COVID-19	-	-	-
Pregnancy	-	-	-
Private reason(s)	-	-	-
Lost to follow-up	-	-	1

Number of subjects in period 1	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg HIV	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg PT	BNT162b2 - Part A Participants Aged 18 to 85 Years - 3 & 30 µg
Started	15	15	30
Completed end of treatment phase	15	15	30
Completed	0	0	0
Not completed	15	15	30
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	2	2
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Roll-over into trial BNT162-14	11	11	10

Non-trial SARS-COV-2 vaccination due to COVID-19	4	2	16
Pregnancy	-	-	-
Private reason(s)	-	-	1
Lost to follow-up	-	-	1

Number of subjects in period 1	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C12	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C14	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg
Started	90	20	12
Completed end of treatment phase	89	19	12
Completed	0	19	12
Not completed	90	1	0
Adverse event, serious fatal	1	-	-
Consent withdrawn by subject	1	1	-
Physician decision	2	-	-
Adverse event, non-fatal	-	-	-
Roll-over into trial BNT162-14	31	-	-
Non-trial SARS-COV-2 vaccination due to COVID-19	55	-	-
Pregnancy	-	-	-
Private reason(s)	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 3 µg
Started	12	12	12
Completed end of treatment phase	12	12	11
Completed	12	12	10
Not completed	0	0	2
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	-
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Roll-over into trial BNT162-14	-	-	-
Non-trial SARS-COV-2 vaccination due to COVID-19	-	-	-
Pregnancy	-	-	-
Private reason(s)	-	-	1
Lost to follow-up	-	-	1

Number of subjects in period 1	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.6 µg SD
Started	12	12	12

Completed end of treatment phase	12	12	11
Completed	12	12	11
Not completed	0	0	1
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	-
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Roll-over into trial BNT162-14	-	-	-
Non-trial SARS-COV-2 vaccination due to COVID-19	-	-	-
Pregnancy	-	-	1
Private reason(s)	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg SD
Started	12
Completed end of treatment phase	12
Completed	11
Not completed	1
Adverse event, serious fatal	-
Consent withdrawn by subject	-
Physician decision	-
Adverse event, non-fatal	-
Roll-over into trial BNT162-14	-
Non-trial SARS-COV-2 vaccination due to COVID-19	-
Pregnancy	-
Private reason(s)	-
Lost to follow-up	1

Baseline characteristics

Reporting groups

Reporting group title	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.1 µg
Reporting group description:	
BNT162a1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen).	
Reporting group title	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.3 µg
Reporting group description:	
BNT162a1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162a1 - Part A Participants Aged 18 to 55 Years - 3 µg
Reporting group description:	
BNT162a1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the Safety Review Committee [SRC]).	
Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 1 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 3 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 10 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 20 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 30 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 50 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 60 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the SRC).	
Reporting group title	BNT162b1 - Part A Participants Aged 56 to 85 Years - 10 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162b1 - Part A Participants Aged 56 to 85 Years - 20 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162b1 - Part A Participants Aged 56 to 85 Years - 30 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 1 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 3 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 10 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 20 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 30 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 56 to 85 Years - 10 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 56 to 85 Years - 20 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 56 to 85 Years - 30 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg HIV

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen), Immunocompromised participants (ICP) expansion cohort (Cohort 13).

Reporting group title	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg PT

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen), ICP expansion cohort (Cohort 13). PT = post-transplant.

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 85 Years - 3 & 30 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen), alternative posology dose group expansion cohort (Cohort 11).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C12

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen), adaptive immune response dose group expansion cohort (C12 = Cohort 12).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C14

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen), B-cell immune response dose group expansion cohort (C14 =

Cohort 14).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg
Reporting group description: BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg
Reporting group description: BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg
Reporting group description: BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 3 µg
Reporting group description: BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg SD
Reporting group description: BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (single dose [SD] regimen).	
Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg SD
Reporting group description: BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (SD regimen).	
Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.6 µg SD
Reporting group description: BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (SD regimen).	
Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg SD
Reporting group description: BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (SD regimen).	

Reporting group values	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 3 µg
Number of subjects	12	12	6
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	50.80	48.31	38.22
standard deviation	± 2.58	± 9.04	± 13.87
Gender categorical Units: Subjects			
Female	5	6	1
Male	7	6	5

Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	12	12	6
Race Units: Subjects			
Asian	0	0	0
Black or African American	0	0	0
White	12	12	5
More than one race	0	0	0
Unknown or Not Reported	0	0	1
Weight Units: kilogram(s)			
arithmetic mean	77.68	72.54	78.58
standard deviation	± 7.59	± 10.85	± 14.93
Body mass index Units: kilogram(s)/square metre			
arithmetic mean	24.61	24.23	24.73
standard deviation	± 3.14	± 2.78	± 2.63

Reporting group values	BNT162b1 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 10 µg
Number of subjects	12	12	12
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	38.21	41.44	43.62
standard deviation	± 10.48	± 11.27	± 11.03
Gender categorical Units: Subjects			
Female	7	6	8
Male	5	6	4
Ethnicity Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	11	12	12
Race Units: Subjects			
Asian	0	0	0
Black or African American	0	0	1
White	12	12	11
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Weight Units: kilogram(s)			
arithmetic mean	72.99	77.11	71.57
standard deviation	± 14.79	± 14.07	± 14.09
Body mass index Units: kilogram(s)/square metre			

arithmetic mean	25.17	24.94	24.20
standard deviation	± 2.89	± 2.68	± 2.32

Reporting group values	BNT162b1 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 30 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 50 µg
Number of subjects	12	12	12
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	39.42	35.74	33.88
standard deviation	± 11.41	± 8.60	± 10.72
Gender categorical Units: Subjects			
Female	4	4	6
Male	8	8	6
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	12	12	12
Race Units: Subjects			
Asian	1	0	0
Black or African American	0	0	0
White	11	12	12
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Weight Units: kilogram(s)			
arithmetic mean	73.58	79.84	76.73
standard deviation	± 11.88	± 13.81	± 13.32
Body mass index Units: kilogram(s)/square metre			
arithmetic mean	24.34	25.68	25.52
standard deviation	± 2.33	± 3.44	± 3.50

Reporting group values	BNT162b1 - Part A Participants Aged 18 to 55 Years - 60 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 20 µg
Number of subjects	12	12	12
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	35.81	64.31	65.66
standard deviation	± 12.50	± 5.89	± 5.95

Gender categorical Units: Subjects			
Female	5	5	10
Male	7	7	2
Ethnicity Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	11	12	12
Race Units: Subjects			
Asian	1	0	0
Black or African American	0	0	0
White	11	12	12
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Weight Units: kilogram(s)			
arithmetic mean	78.70	71.90	70.38
standard deviation	± 13.85	± 10.98	± 9.14
Body mass index Units: kilogram(s)/square metre			
arithmetic mean	25.19	24.73	25.59
standard deviation	± 3.09	± 2.46	± 2.22

Reporting group values	BNT162b1 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 3 µg
Number of subjects	12	12	12
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	67.16	36.65	39.64
standard deviation	± 6.47	± 10.14	± 10.14
Gender categorical Units: Subjects			
Female	8	5	7
Male	4	7	5
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	12	12	12
Race Units: Subjects			
Asian	0	0	0
Black or African American	0	0	0
White	12	12	12
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Weight			
Units: kilogram(s)			
arithmetic mean	69.98	80.18	77.08
standard deviation	± 8.06	± 14.13	± 10.84
Body mass index			
Units: kilogram(s)/square metre			
arithmetic mean	25.63	25.25	25.50
standard deviation	± 2.22	± 3.26	± 2.79

Reporting group values	BNT162b2 - Part A Participants Aged 18 to 55 Years - 10 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 30 µg
Number of subjects	12	12	12
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	35.07	42.75	47.21
standard deviation	± 10.46	± 9.89	± 6.43
Gender categorical			
Units: Subjects			
Female	8	10	4
Male	4	2	8
Ethnicity			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	12	12	12
Race			
Units: Subjects			
Asian	0	0	0
Black or African American	0	0	0
White	12	12	12
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Weight			
Units: kilogram(s)			
arithmetic mean	76.11	72.45	77.78
standard deviation	± 11.67	± 10.97	± 8.43
Body mass index			
Units: kilogram(s)/square metre			
arithmetic mean	25.13	25.43	25.01
standard deviation	± 2.07	± 2.34	± 1.38

Reporting group values	BNT162b2 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 20 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 30 µg
Number of subjects	12	12	12
Age categorical			
Units: Subjects			

Age continuous Units: years			
arithmetic mean	65.44	65.88	63.87
standard deviation	± 7.42	± 6.56	± 5.42
Gender categorical Units: Subjects			
Female	4	6	8
Male	8	6	4
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	12	12	12
Race Units: Subjects			
Asian	0	0	0
Black or African American	0	0	0
White	12	12	12
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Weight Units: kilogram(s)			
arithmetic mean	77.87	76.91	75.80
standard deviation	± 9.78	± 12.38	± 11.98
Body mass index Units: kilogram(s)/square metre			
arithmetic mean	25.43	25.62	25.85
standard deviation	± 2.15	± 2.47	± 2.75

Reporting group values	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg HIV	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg PT	BNT162b2 - Part A Participants Aged 18 to 85 Years - 3 & 30 µg
Number of subjects	15	15	30
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	48.04	48.93	51.92
standard deviation	± 10.36	± 11.87	± 13.57
Gender categorical Units: Subjects			
Female	3	9	13
Male	12	6	17
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	15	15	30
Race Units: Subjects			
Asian	1	0	0
Black or African American	0	0	0

White	14	15	30
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Weight			
Units: kilogram(s)			
arithmetic mean	73.85	73.50	77.79
standard deviation	± 9.67	± 10.07	± 12.92
Body mass index			
Units: kilogram(s)/square metre			
arithmetic mean	23.62	25.63	25.53
standard deviation	± 1.90	± 2.82	± 2.72

Reporting group values	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C12	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C14	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg
Number of subjects	90	20	12
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	55.59	48.45	36.42
standard deviation	± 16.07	± 13.87	± 10.33
Gender categorical			
Units: Subjects			
Female	45	10	8
Male	45	10	4
Ethnicity			
Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	89	20	12
Race			
Units: Subjects			
Asian	0	1	1
Black or African American	1	0	0
White	89	19	11
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Weight			
Units: kilogram(s)			
arithmetic mean	75.44	79.09	67.45
standard deviation	± 13.02	± 14.94	± 13.53
Body mass index			
Units: kilogram(s)/square metre			
arithmetic mean	25.08	26.12	23.31
standard deviation	± 2.73	± 2.96	± 2.38

Reporting group values	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 3 µg
Number of subjects	12	12	12

Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	39.41	34.47	35.42
standard deviation	± 12.34	± 10.24	± 9.68
Gender categorical Units: Subjects			
Female	5	3	8
Male	7	9	4
Ethnicity Units: Subjects			
Hispanic or Latino	0	2	0
Not Hispanic or Latino	12	10	12
Race Units: Subjects			
Asian	0	0	0
Black or African American	0	0	0
White	11	12	12
More than one race	1	0	0
Unknown or Not Reported	0	0	0
Weight Units: kilogram(s)			
arithmetic mean	76.41	72.44	70.94
standard deviation	± 15.66	± 6.86	± 11.43
Body mass index Units: kilogram(s)/square metre			
arithmetic mean	25.02	23.83	25.06
standard deviation	± 2.85	± 2.39	± 3.73

Reporting group values	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.6 µg SD
Number of subjects	12	12	12
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	40.03	35.23	42.40
standard deviation	± 14.67	± 11.88	± 12.04
Gender categorical Units: Subjects			
Female	10	8	5
Male	2	4	7
Ethnicity Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	12	11	12
Race			

Units: Subjects			
Asian	0	1	0
Black or African American	0	0	0
White	12	11	12
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Weight			
Units: kilogram(s)			
arithmetic mean	63.75	73.26	73.48
standard deviation	± 6.14	± 15.39	± 9.51
Body mass index			
Units: kilogram(s)/square metre			
arithmetic mean	22.82	24.97	24.19
standard deviation	± 1.54	± 3.17	± 2.04

Reporting group values	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg SD	Total	
Number of subjects	12	512	
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	32.60		
standard deviation	± 10.87	-	
Gender categorical			
Units: Subjects			
Female	7	261	
Male	5	251	
Ethnicity			
Units: Subjects			
Hispanic or Latino	0	6	
Not Hispanic or Latino	12	506	
Race			
Units: Subjects			
Asian	0	6	
Black or African American	0	2	
White	12	502	
More than one race	0	1	
Unknown or Not Reported	0	1	
Weight			
Units: kilogram(s)			
arithmetic mean	68.90		
standard deviation	± 11.56	-	
Body mass index			
Units: kilogram(s)/square metre			
arithmetic mean	24.04		
standard deviation	± 2.59	-	

End points

End points reporting groups

Reporting group title	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.1 µg
Reporting group description:	
BNT162a1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen).	
Reporting group title	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.3 µg
Reporting group description:	
BNT162a1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162a1 - Part A Participants Aged 18 to 55 Years - 3 µg
Reporting group description:	
BNT162a1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the Safety Review Committee [SRC]).	
Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 1 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 3 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 10 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 20 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 30 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 50 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 60 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the SRC).	
Reporting group title	BNT162b1 - Part A Participants Aged 56 to 85 Years - 10 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162b1 - Part A Participants Aged 56 to 85 Years - 20 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	
Reporting group title	BNT162b1 - Part A Participants Aged 56 to 85 Years - 30 µg
Reporting group description:	
BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).	

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 1 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 3 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 10 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 20 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 30 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 56 to 85 Years - 10 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 56 to 85 Years - 20 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 56 to 85 Years - 30 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg HIV

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen), Immunocompromised participants (ICP) expansion cohort (Cohort 13).

Reporting group title	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg PT

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen), ICP expansion cohort (Cohort 13). PT = post-transplant.

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 85 Years - 3 & 30 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen), alternative posology dose group expansion cohort (Cohort 11).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C12

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen), adaptive immune response dose group expansion cohort (C12 = Cohort 12).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C14

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen), B-cell immune response dose group expansion cohort (C14 =

Cohort 14).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg

Reporting group description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg

Reporting group description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg

Reporting group description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 3 µg

Reporting group description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg SD

Reporting group description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (single dose [SD] regimen).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg SD

Reporting group description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (SD regimen).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.6 µg SD

Reporting group description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (SD regimen).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg SD

Reporting group description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (SD regimen).

Primary: Number of Participants With Solicited Local Reactions at the Injection Site (Pain, Tenderness, Erythema/Redness, Induration/Swelling) Recorded up to 7 Days After Each IMP Dose

End point title	Number of Participants With Solicited Local Reactions at the Injection Site (Pain, Tenderness, Erythema/Redness, Induration/Swelling) Recorded up to 7 Days After Each IMP Dose[1]

End point description:

Solicited local reactions at the injection site (pain, tenderness, erythema/redness, and induration/swelling) were monitored and graded using criteria based on the guidance given in US FDA Guidance for Industry "Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials". The reporting of local reactions was based on the participant's assessments via daily solicited reports in the participant diaries. Safety Set - all participants who received at least one dose of the IMP. 'Prime to D7' below indicates Prime up to Day 7 after Prime, 'Boost to D7' below indicates Boost up to Day 7 after Boost. 999 indicates data not available as the boost immunization was withheld for the BNT162a1 3 µg cohort and the BNT162b1 60 µg younger cohort following Safety Review Committee (SRC) decision. 9999 indicates data not available as the boost immunization was not administered to the BNT162c2 SD regimen cohorts.

End point type	Primary

End point timeframe:

From Day 1 to Day 8 for Dose 1 (Prime Immunization) and from Day 22 to Day 29 for Dose 2 (Boost Immunization)

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: No statistical analysis was planned for this endpoint.

End point values	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 1 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	6	12
Units: Participants				
Prime to D7: any local reaction	9	11	6	6
Prime to D7: any severe/grade ≥3 local reaction	0	0	0	0
Boost to D7: any local reaction	3	10	999	7
Boost to D7: any severe/grade ≥3 local reaction	0	0	999	2

End point values	BNT162b1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 10 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Prime to D7: any local reaction	5	10	12	11
Prime to D7: any severe/grade ≥3 local reaction	0	1	2	4
Boost to D7: any local reaction	5	10	11	11
Boost to D7: any severe/grade ≥3 local reaction	0	0	0	2

End point values	BNT162b1 - Part A Participants Aged 18 to 55 Years - 50 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 60 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 20 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Prime to D7: any local reaction	12	12	7	11
Prime to D7: any severe/grade ≥3 local reaction	2	1	0	0
Boost to D7: any local reaction	11	999	8	9
Boost to D7: any severe/grade ≥3 local reaction	3	999	0	0

End point values	BNT162b1 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 10 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Prime to D7: any local reaction	11	6	9	12
Prime to D7: any severe/grade ≥3 local reaction	0	0	0	0
Boost to D7: any local reaction	9	4	8	10
Boost to D7: any severe/grade ≥3 local reaction	0	0	0	0

End point values	BNT162b2 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 30 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 20 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Prime to D7: any local reaction	12	10	7	9
Prime to D7: any severe/grade ≥3 local reaction	0	0	0	0
Boost to D7: any local reaction	10	11	7	8
Boost to D7: any severe/grade ≥3 local reaction	0	0	1	0

End point values	BNT162b2 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg HIV	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg PT	BNT162b2 - Part A Participants Aged 18 to 85 Years - 3 & 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	15	15	30
Units: Participants				
Prime to D7: any local reaction	9	12	14	16
Prime to D7: any severe/grade ≥3 local reaction	0	0	0	0
Boost to D7: any local reaction	10	12	11	27
Boost to D7: any severe/grade ≥3 local reaction	1	0	0	2

End point values	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C12	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C14	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	90	20	12	12
Units: Participants				
Prime to D7: any local reaction	82	20	4	3
Prime to D7: any severe/grade ≥3 local reaction	1	0	0	0
Boost to D7: any local reaction	79	19	3	5
Boost to D7: any severe/grade ≥3 local reaction	2	1	0	0

End point values	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg SD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Prime to D7: any local reaction	8	11	4	7
Prime to D7: any severe/grade ≥3 local reaction	0	0	0	0
Boost to D7: any local reaction	7	8	9999	9999
Boost to D7: any severe/grade ≥3 local reaction	0	0	9999	9999

End point values	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.6 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg SD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	12		
Units: Participants				
Prime to D7: any local reaction	5	11		
Prime to D7: any severe/grade ≥3 local reaction	0	0		
Boost to D7: any local reaction	9999	9999		
Boost to D7: any severe/grade ≥3 local reaction	9999	9999		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Solicited Systemic Reactions (Nausea, Vomiting, Diarrhea, Headache, Fatigue, Myalgia, Arthralgia, Chills, Loss of Appetite, Malaise, and Fever) Recorded up to 7 Days After Each IMP Dose

End point title	Number of Participants With Solicited Systemic Reactions (Nausea, Vomiting, Diarrhea, Headache, Fatigue, Myalgia, Arthralgia, Chills, Loss of Appetite, Malaise, and Fever) Recorded up to 7 Days After Each IMP Dose[2]

End point description:

Solicited systemic reactions (nausea, vomiting, diarrhea, headache, fatigue, myalgia, arthralgia, chills, loss of appetite, malaise, and fever) were monitored and graded using criteria based on the guidance given in US FDA Guidance for Industry "Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials". The reporting of systemic reactions was based on the participant's assessments via daily solicited reports in the participant diaries. Safety Set - all participants who received at least one dose of the IMP. Prime to D7 below indicates Prime up to Day 7 after Prime, Boost to D7 below indicates Boost up to Day 7 after Boost. 999 indicates data not available as the boost immunization was withheld for the BNT162a1 3 µg cohort and the BNT162b1 60 µg younger cohort following SRC decision. 9999 indicates data not available as the boost immunization was not administered to the BNT162c2 SD regimen cohorts.

End point type	Primary

End point timeframe:

From Day 1 to Day 8 for Dose 1 (Prime Immunization) and from Day 22 to Day 29 for Dose 2 (Boost Immunization)

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: No statistical analysis was planned for this endpoint.

End point values	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 1 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	6	12
Units: Participants				
Prime to D7: any local reaction	6	12	6	9
Prime to D7: any severe/grade ≥3 local reaction	1	1	5	0
Boost to D7: any local reaction	3	12	999	7
Boost to D7: any severe/grade ≥3 local reaction	0	4	999	3

End point values	BNT162b1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 10 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Prime to D7: any local reaction	8	8	11	11
Prime to D7: any severe/grade ≥3 local reaction	0	1	2	3
Boost to D7: any local reaction	7	9	10	11

Boost to D7: any severe/grade ≥3 local reaction	1	5	5	6

End point values	BNT162b1 - Part A Participants Aged 18 to 55 Years - 50 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 60 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 20 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Prime to D7: any local reaction	12	12	9	10
Prime to D7: any severe/grade ≥3 local reaction	5	8	1	1
Boost to D7: any local reaction	11	999	8	10
Boost to D7: any severe/grade ≥3 local reaction	5	999	2	2

End point values	BNT162b1 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 10 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Prime to D7: any local reaction	11	9	9	12
Prime to D7: any severe/grade ≥3 local reaction	2	0	0	0
Boost to D7: any local reaction	12	4	2	7
Boost to D7: any severe/grade ≥3 local reaction	4	0	0	1

End point values	BNT162b2 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 30 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 20 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Prime to D7: any local reaction	9	9	3	4
Prime to D7: any severe/grade ≥3 local reaction	1	0	1	0
Boost to D7: any local reaction	10	10	4	8
Boost to D7: any severe/grade ≥3 local reaction	1	3	1	0

End point values	BNT162b2 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg HIV	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg PT	BNT162b2 - Part A Participants Aged 18 to 85 Years - 3 & 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	15	15	30
Units: Participants				
Prime to D7: any local reaction	9	12	14	12
Prime to D7: any severe/grade ≥3 local reaction	0	1	0	0
Boost to D7: any local reaction	11	13	12	21
Boost to D7: any severe/grade ≥3 local reaction	2	4	1	4

End point values	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C12	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C14	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	90	20	12	12
Units: Participants				
Prime to D7: any local reaction	68	15	5	8
Prime to D7: any severe/grade ≥3 local reaction	5	0	0	0
Boost to D7: any local reaction	78	16	3	7
Boost to D7: any severe/grade ≥3 local reaction	14	3	1	1

End point values	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg SD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
Prime to D7: any local reaction	9	12	7	7
Prime to D7: any severe/grade ≥3 local reaction	1	1	0	2
Boost to D7: any local reaction	6	9	9999	9999
Boost to D7: any severe/grade ≥3 local reaction	0	2	9999	9999

End point values	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.6 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg SD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	12		
Units: Participants				
Prime to D7: any local reaction	4	8		
Prime to D7: any severe/grade ≥3 local reaction	0	2		
Boost to D7: any local reaction	9999	9999		
Boost to D7: any severe/grade ≥3 local reaction	9999	9999		

Statistical analyses

No statistical analyses for this end point

Primary: The Percentage of Participants With at Least 1 Unsolicited Treatment Emergent Adverse Event (TEAE) Occurring After Dose 1 (Prime Immunization) up to Dose 2 (Boost Immunization) or 28 Days After Dose 1

End point title	The Percentage of Participants With at Least 1 Unsolicited Treatment Emergent Adverse Event (TEAE) Occurring After Dose 1 (Prime Immunization) up to Dose 2 (Boost Immunization) or 28 Days After Dose 1[3]

End point description:

TEAEs without AEs based on solicited reporting via diaries, were analyzed by vaccine, age group, dose level, and for each IMP dose. The percentage of participants reporting at least one TEAE was summarized by adverse event types (any TEAE and any grade ≥3 TEAE) using the Safety Set. Safety Set - all participants who received at least one dose of the IMP.

End point type	Primary

End point timeframe:

28 days following Dose 1 or up to Dose 2 (whichever was first)

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: No statistical analysis was planned for this endpoint.

End point values	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 1 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	6	12
Units: Percentage of participants				
number (not applicable)				
Any TEAE	8	33	83	8
Any grade ≥3 TEAE	0	0	0	0

End point values	BNT162b1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 10 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Percentage of participants				
number (not applicable)				
Any TEAE	0	50	33	42
Any grade ≥3 TEAE	0	0	8	0

End point values	BNT162b1 - Part A Participants Aged 18 to 55 Years - 50 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 60 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 20 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Percentage of participants				
number (not applicable)				
Any TEAE	42	58	25	17
Any grade ≥3 TEAE	0	0	8	8

End point values	BNT162b1 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 10 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Percentage of participants				
number (not applicable)				
Any TEAE	58	25	50	50
Any grade ≥3 TEAE	8	0	0	8

End point values	BNT162b2 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 30 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 20 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Percentage of participants				
number (not applicable)				

Any TEAE	8	42	25	33
Any grade ≥3 TEAE	0	0	0	0

End point values	BNT162b2 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg HIV	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg PT	BNT162b2 - Part A Participants Aged 18 to 85 Years - 3 & 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	15	15	30
Units: Percentage of participants				
number (not applicable)				
Any TEAE	25	7	53	13
Any grade ≥3 TEAE	17	0	7	0

End point values	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C12	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C14	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	90	20	12	12
Units: Percentage of participants				
number (not applicable)				
Any TEAE	26	35	17	33
Any grade ≥3 TEAE	2	5	0	0

End point values	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg SD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Percentage of participants				
number (not applicable)				
Any TEAE	17	17	50	58
Any grade ≥3 TEAE	0	8	0	0

End point values	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.6 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg		

	SD	SD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	12		
Units: Percentage of participants				
number (not applicable)				
Any TEAE	25	25		
Any grade ≥3 TEAE	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: The Percentage of Participants With at Least 1 Unsolicited TEAE Occurring After Dose 1 up to 28 Days After Dose 2 (Boost Immunization) or After Dose 1 (Prime Immunization) (if no Dose 2)

End point title	The Percentage of Participants With at Least 1 Unsolicited TEAE Occurring After Dose 1 up to 28 Days After Dose 2 (Boost Immunization) or After Dose 1 (Prime Immunization) (if no Dose 2)[4][5]

End point description:

TEAEs, without AEs based on solicited reporting via diaries, were analyzed by vaccine, age group, dose level, and for each IMP dose. The percentage of participants reporting at least one TEAE was summarized by adverse event types (any TEAE and any grade ≥3 TEAE) using the Safety Set. Safety Set - all participants who received at least one dose of the IMP. Per study protocol, this endpoint was only applicable for arms planned to receive two doses.

End point type	Primary

End point timeframe:

28 days following Dose 2 or Dose 1 (if no Dose 2 was given)

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: No statistical analysis was planned for this endpoint.

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data for the BNT162c2 Single Dose Cohorts are not reported for this endpoint as no Boost dose was planned.

End point values	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 1 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	6	12
Units: Percentage of participants				
number (not applicable)				
Any TEAE	17	33	83	58
Any grade ≥3 TEAE	0	0	0	0

End point values	BNT162b1 - Part A Participants	BNT162b1 - Part A Participants	BNT162b1 - Part A Participants	BNT162b1 - Part A Participants

	Aged 18 to 55 Years - 3 µg	Aged 18 to 55 Years - 10 µg	Aged 18 to 55 Years - 20 µg	Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Percentage of participants				
number (not applicable)				
Any TEAE	8	75	50	58
Any grade ≥3 TEAE	0	0	25	0

End point values	BNT162b1 - Part A Participants Aged 18 to 55 Years - 50 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 60 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 20 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Percentage of participants				
number (not applicable)				
Any TEAE	67	58	25	33
Any grade ≥3 TEAE	0	0	8	8

End point values	BNT162b1 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 10 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Percentage of participants				
number (not applicable)				
Any TEAE	75	58	58	67
Any grade ≥3 TEAE	17	0	0	8

End point values	BNT162b2 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 30 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 20 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Percentage of participants				
number (not applicable)				
Any TEAE	25	50	33	58
Any grade ≥3 TEAE	0	8	8	8

End point values	BNT162b2 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg HIV	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg PT	BNT162b2 - Part A Participants Aged 18 to 85 Years - 3 & 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	15	15	30
Units: Percentage of participants				
number (not applicable)				
Any TEAE	33	13	73	40
Any grade ≥3 TEAE	17	0	7	3

End point values	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C12	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C14	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	90	20	12	12
Units: Percentage of participants				
number (not applicable)				
Any TEAE	49	45	33	42
Any grade ≥3 TEAE	4	10	0	8

End point values	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 3 µg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	12		
Units: Percentage of participants				
number (not applicable)				
Any TEAE	33	17		
Any grade ≥3 TEAE	0	8		

Statistical analyses

No statistical analyses for this end point

Secondary: Functional Antibody Responses (Titers) for BNT162a1, BNT162b1, BNT162b2 (Younger and Older Dose Ranging Cohorts), and BNT162c2 (P/B)

End point title	Functional Antibody Responses (Titers) for BNT162a1, BNT162b1, BNT162b2 (Younger and Older Dose Ranging Cohorts), and BNT162c2 (P/B)[6]

End point description:

At Day 1 (Baseline) and at 7 and 21 days after Dose 1 (Prime Immunization) and at 7, 21, 28, 63, and

162 days after Dose 2 (Boost Immunization). Immunogenicity set - all participants who received at least one dose of IMP and had at least one postbaseline functional antibody titer immunogenicity assessment. 9999 indicates data not available as Day 29 and/or Day 50 were scheduled before approval of protocol version 7 which implemented these visits. 999 indicates confidence interval not calculated as values of at least 3 participants were not available.

End point type	Secondary

End point timeframe:

Up to 183 days following Dose 1

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only reports data for the BNT162a1, BNT162b1, BNT162b2 Dose Ranging, and BNT162c2 Prime/Boost Cohorts.

End point values	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 1 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	6	12
Units: Titer				
geometric mean (confidence interval 95%)				
Pre-Prime Immunization (Day 1)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)
7 days after Prime Immunization (Day 8)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)
21 days after Prime Immunization (Day 22)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	10.0 (6.1 to 16.3)
7 days after Boost Immunization (Day 29)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)
21 days after Boost Immunization (Day 43)	5.0 (5.0 to 5.0)	8.7 (3.8 to 19.8)	5.3 (4.6 to 6.1)	69.2 (33.0 to 145.4)
28 days after Boost Immunization (Day 50)	5.0 (-999 to 999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)
63 days after Boost Immunization (Day 85)	5.0 (5.0 to 5.0)	7.5 (3.9 to 14.5)	5.0 (5.0 to 5.0)	25.9 (14.6 to 46.0)
162 days after Boost Immunization (Day 184)	5.0 (5.0 to 5.0)	6.9 (3.4 to 13.8)	5.0 (5.0 to 5.0)	10.0 (6.1 to 16.4)

End point values	BNT162b1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 10 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Titer				
geometric mean (confidence interval 95%)				
Pre-Prime Immunization (Day 1)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)
7 days after Prime Immunization (Day 8)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)
21 days after Prime Immunization (Day 22)	6.9 (4.4 to 10.7)	10.0 (5.4 to 18.5)	11.7 (6.2 to 22.1)	29.1 (13.5 to 63.0)
7 days after Boost Immunization (Day 29)	55.0 (32.5 to 93.1)	9999 (9999 to 9999)	181.5 (107.5 to 306.3)	9999 (9999 to 9999)

21 days after Boost Immunization (Day 43)	95.1 (47.0 to 192.7)	62.2 (30.4 to 127.0)	160.0 (90.3 to 283.6)	184.9 (96.8 to 353.0)
28 days after Boost Immunization (Day 50)	80.0 (36.1 to 177.5)	9999 (9999 to 9999)	82.3 (37.4 to 181.1)	9999 (9999 to 9999)
63 days after Boost Immunization (Day 85)	31.7 (14.5 to 69.4)	40.0 (21.1 to 76.0)	134.5 (70.0 to 258.6)	102.9 (58.1 to 182.2)
162 days after Boost Immunization (Day 184)	15.0 (9.0 to 24.8)	13.7 (8.8 to 21.4)	27.4 (14.0 to 53.6)	29.2 (13.9 to 61.2)

End point values	BNT162b1 - Part A Participants Aged 18 to 55 Years - 50 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 60 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 20 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Titer				
geometric mean (confidence interval 95%)				
Pre-Prime Immunization (Day 1)	5.1 (4.8 to 5.5)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)
7 days after Prime Immunization (Day 8)	5.1 (4.8 to 5.5)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)
21 days after Prime Immunization (Day 22)	20.6 (11.5 to 37.0)	13.7 (7.5 to 25.3)	16.3 (7.7 to 34.5)	15.4 (7.8 to 30.4)
7 days after Boost Immunization (Day 29)	9999 (9999 to 9999)	9999 (9999 to 9999)	320.0 (183.6 to 557.7)	169.5 (70.3 to 408.7)
21 days after Boost Immunization (Day 43)	282.1 (136.8 to 581.6)	8.9 (6.1 to 13.0)	293.4 (179.9 to 478.5)	95.1 (42.3 to 214.0)
28 days after Boost Immunization (Day 50)	9999 (9999 to 9999)	9999 (9999 to 9999)	226.3 (120.5 to 424.8)	89.8 (37.5 to 214.9)
63 days after Boost Immunization (Day 85)	120.5 (56.1 to 258.7)	7.7 (5.2 to 11.4)	46.2 (25.4 to 84.0)	33.6 (16.6 to 68.1)
162 days after Boost Immunization (Day 184)	56.6 (22.3 to 143.6)	5.2 (4.8 to 5.5)	16.8 (10.0 to 28.2)	19.4 (10.7 to 35.1)

End point values	BNT162b1 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 10 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Titer				
geometric mean (confidence interval 95%)				
Pre-Prime Immunization (Day 1)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)
7 days after Prime Immunization (Day 8)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)
21 days after Prime Immunization (Day 22)	16.3 (8.3 to 32.3)	5.3 (4.7 to 6.0)	7.5 (5.6 to 10.1)	16.6 (9.7 to 28.3)
7 days after Boost Immunization (Day 29)	207.5 (94.0 to 458.0)	38.9 (16.1 to 93.5)	134.5 (82.2 to 220.1)	40.0 (-999 to 999)
21 days after Boost Immunization (Day 43)	134.5 (66.8 to 270.8)	49.9 (26.9 to 92.6)	109.9 (71.1 to 169.8)	187.3 (119.9 to 292.6)

28 days after Boost Immunization (Day 50)	95.1 (50.9 to 178.0)	36.4 (20.8 to 63.8)	67.3 (35.7 to 126.7)	190.3 (118.4 to 305.7)
63 days after Boost Immunization (Day 85)	69.2 (33.8 to 142.0)	36.4 (19.3 to 68.6)	33.6 (19.9 to 57.0)	145.6 (85.5 to 247.8)
162 days after Boost Immunization (Day 184)	65.4 (31.7 to 134.8)	8.5 (5.6 to 13.0)	11.2 (7.8 to 16.2)	21.3 (12.2 to 37.3)

End point values	BNT162b2 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 30 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 20 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Titer				
geometric mean (confidence interval 95%)				
Pre-Prime Immunization (Day 1)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)
7 days after Prime Immunization (Day 8)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)
21 days after Prime Immunization (Day 22)	16.3 (8.0 to 33.5)	15.9 (9.6 to 26.2)	8.4 (5.6 to 12.6)	7.9 (5.2 to 12.1)
7 days after Boost Immunization (Day 29)	213.6 (114.7 to 397.7)	329.4 (203.2 to 533.9)	127.0 (79.2 to 203.7)	164.7 (77.0 to 352.0)
21 days after Boost Immunization (Day 43)	164.7 (89.3 to 303.6)	300.5 (182.7 to 494.1)	134.5 (85.4 to 214.1)	169.5 (115.3 to 249.2)
28 days after Boost Immunization (Day 50)	160.0 (84.6 to 302.5)	213.6 (148.8 to 306.6)	127.0 (75.7 to 213.0)	132.4 (91.8 to 191.0)
63 days after Boost Immunization (Day 85)	146.7 (80.9 to 265.9)	160.0 (97.4 to 263.0)	21.8 (12.1 to 39.2)	27.4 (17.5 to 42.9)
162 days after Boost Immunization (Day 184)	54.8 (31.5 to 95.5)	38.9 (20.6 to 73.2)	26.7 (14.1 to 50.4)	15.5 (11.8 to 20.5)

End point values	BNT162b2 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Titer				
geometric mean (confidence interval 95%)				
Pre-Prime Immunization (Day 1)	6.9 (3.4 to 13.8)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)
7 days after Prime Immunization (Day 8)	8.2 (2.8 to 24.1)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)
21 days after Prime Immunization (Day 22)	49.0 (18.3 to 131.4)	5.0 (5.0 to 5.0)	5.3 (4.7 to 6.0)	5.3 (4.7 to 6.0)
7 days after Boost Immunization (Day 29)	678.1 (395.9 to 1161.2)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.3 (4.7 to 6.0)
21 days after Boost Immunization (Day 43)	452.5 (255.6 to 801.1)	5.1 (4.8 to 5.5)	5.6 (4.9 to 6.5)	5.7 (4.8 to 6.6)
28 days after Boost Immunization (Day 50)	391.7 (229.4 to 668.8)	5.0 (5.0 to 5.0)	5.9 (5.0 to 7.1)	5.0 (5.0 to 5.0)

63 days after Boost Immunization (Day 85)	80.0 (39.1 to 163.5)	5.6 (5.0 to 6.3)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)
162 days after Boost Immunization (Day 184)	58.4 (30.6 to 111.3)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.8 (4.2 to 7.9)

End point values	BNT162c2 - Part A Participants Aged 18 to 55 Years - 3 µg			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Titer				
geometric mean (confidence interval 95%)				
Pre-Prime Immunization (Day 1)	5.0 (5.0 to 5.0)			
7 days after Prime Immunization (Day 8)	5.0 (5.0 to 5.0)			
21 days after Prime Immunization (Day 22)	7.1 (4.9 to 10.2)			
7 days after Boost Immunization (Day 29)	8.0 (4.8 to 13.4)			
21 days after Boost Immunization (Day 43)	6.0 (4.6 to 8.0)			
28 days after Boost Immunization (Day 50)	5.3 (4.7 to 6.0)			
63 days after Boost Immunization (Day 85)	5.2 (4.7 to 5.8)			
162 days after Boost Immunization (Day 184)	10.4 (3.4 to 31.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Fold Increase in Functional Antibody Titers as Compared to Baseline for BNT162a1, BNT162b1, BNT162b2 (Younger and Older Dose Ranging Cohorts), and BNT162c2 (P/B)

End point title	Fold Increase in Functional Antibody Titers as Compared to Baseline for BNT162a1, BNT162b1, BNT162b2 (Younger and Older Dose Ranging Cohorts), and BNT162c2 (P/B)[7]

End point description:

At 7 and 21 days after Dose 1 (Prime Immunization) and at 7, 21, 28, 63, and 162 days after Dose 2 (Boost Immunization). Immunogenicity set - all participants who received at least one dose of IMP and had at least one postbaseline functional antibody titer immunogenicity assessment. 9999 indicates data not available as Day 29 and/or Day 50 were scheduled before approval of protocol version 7 which implemented these visits. 999 indicates confidence interval not calculated as values of at least 3 participants were not available.

End point type	Secondary

End point timeframe:

Up to 183 days following Dose 1

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only reports data for the BNT162a1, BNT162b1, BNT162b2 Dose Ranging, and BNT162c2 Prime/Boost Cohorts.

End point values	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 1 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	6	12
Units: Titer				
geometric mean (confidence interval 95%)				
7 days after Prime Immunization (Day 8)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)
21 days after Prime Immunization (Day 22)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	2.0 (1.2 to 3.3)
7 days after Boost Immunization (Day 29)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)
21 days after Boost Immunization (Day 43)	1.0 (1.0 to 1.0)	1.7 (0.8 to 4.0)	1.1 (0.9 to 1.2)	13.8 (6.6 to 29.1)
28 days after Boost Immunization (Day 50)	1.0 (-999 to 999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)
63 days after Boost Immunization (Day 85)	1.0 (1.0 to 1.0)	1.5 (0.8 to 2.9)	1.0 (1.0 to 1.0)	5.2 (2.9 to 9.2)
162 days after Boost Immunization (Day 184)	1.0 (1.0 to 1.0)	1.4 (0.7 to 2.8)	1.0 (1.0 to 1.0)	2.0 (1.2 to 3.3)

End point values	BNT162b1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 10 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Titer				
geometric mean (confidence interval 95%)				
7 days after Prime Immunization (Day 8)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)
21 days after Prime Immunization (Day 22)	1.4 (0.9 to 2.1)	2.0 (1.1 to 3.7)	2.3 (1.2 to 4.4)	5.8 (2.7 to 12.6)
7 days after Boost Immunization (Day 29)	11.0 (6.5 to 18.6)	9999 (9999 to 9999)	36.3 (21.5 to 61.3)	9999 (9999 to 9999)
21 days after Boost Immunization (Day 43)	19.0 (9.4 to 38.5)	12.4 (6.1 to 25.4)	32.0 (18.1 to 56.7)	37.0 (19.4 to 70.6)
28 days after Boost Immunization (Day 50)	16.0 (7.2 to 35.5)	9999 (9999 to 9999)	16.5 (7.5 to 36.2)	9999 (9999 to 9999)
63 days after Boost Immunization (Day 85)	6.3 (2.9 to 13.9)	8.0 (4.2 to 15.2)	26.9 (14.0 to 51.7)	20.6 (11.6 to 36.4)
162 days after Boost Immunization (Day 184)	3.0 (1.8 to 5.0)	2.7 (1.8 to 4.3)	5.5 (2.8 to 10.7)	5.8 (2.8 to 12.2)

End point values	BNT162b1 - Part A Participants Aged 18 to 55 Years - 50 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 60 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 20 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Titer				
geometric mean (confidence interval 95%)				
7 days after Prime Immunization (Day 8)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)
21 days after Prime Immunization (Day 22)	4.0 (2.2 to 7.3)	2.7 (1.5 to 5.1)	3.3 (1.5 to 6.9)	3.1 (1.6 to 6.1)
7 days after Boost Immunization (Day 29)	9999 (9999 to 9999)	9999 (9999 to 9999)	64.0 (36.7 to 111.5)	33.9 (14.1 to 81.7)
21 days after Boost Immunization (Day 43)	54.7 (26.5 to 112.8)	1.8 (1.2 to 2.6)	58.7 (36.0 to 95.7)	19.0 (8.5 to 42.8)
28 days after Boost Immunization (Day 50)	9999 (9999 to 9999)	9999 (9999 to 9999)	45.3 (24.1 to 85.0)	18.0 (7.5 to 43.0)
63 days after Boost Immunization (Day 85)	23.4 (10.8 to 50.4)	1.5 (1.0 to 2.3)	9.2 (5.1 to 16.8)	6.7 (3.3 to 13.6)
162 days after Boost Immunization (Day 184)	11.0 (4.3 to 28.2)	1.0 (1.0 to 1.1)	3.4 (2.0 to 5.6)	3.9 (2.1 to 7.0)

End point values	BNT162b1 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 10 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Titer				
geometric mean (confidence interval 95%)				
7 days after Prime Immunization (Day 8)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)
21 days after Prime Immunization (Day 22)	3.3 (1.7 to 6.5)	1.1 (0.9 to 1.2)	1.5 (1.1 to 2.0)	3.3 (1.9 to 5.7)
7 days after Boost Immunization (Day 29)	41.5 (18.8 to 91.6)	7.8 (3.2 to 18.7)	26.9 (16.4 to 44.0)	8.0 (-999 to 999)
21 days after Boost Immunization (Day 43)	26.9 (13.4 to 54.2)	10.0 (5.4 to 18.5)	22.0 (14.2 to 34.0)	37.5 (24.0 to 58.5)
28 days after Boost Immunization (Day 50)	19.0 (10.2 to 35.6)	7.3 (4.2 to 12.8)	13.5 (7.1 to 25.3)	38.1 (23.7 to 61.1)
63 days after Boost Immunization (Day 85)	13.8 (6.8 to 28.4)	7.3 (3.9 to 13.7)	6.7 (4.0 to 11.4)	29.1 (17.1 to 49.6)
162 days after Boost Immunization (Day 184)	13.1 (6.3 to 27.0)	1.7 (1.1 to 2.6)	2.2 (1.6 to 3.2)	4.3 (2.4 to 7.5)

End point values	BNT162b2 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 30 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 20 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Titer				
geometric mean (confidence interval 95%)				
7 days after Prime Immunization (Day 8)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)
21 days after Prime Immunization (Day 22)	3.3 (1.6 to 6.7)	3.2 (1.9 to 5.2)	1.7 (1.1 to 2.5)	1.6 (1.0 to 2.4)
7 days after Boost Immunization (Day 29)	42.7 (22.9 to 79.5)	65.9 (40.6 to 106.8)	25.4 (15.8 to 40.7)	32.9 (15.4 to 70.4)
21 days after Boost Immunization (Day 43)	32.9 (17.9 to 60.7)	60.1 (36.5 to 98.8)	26.9 (16.9 to 42.8)	33.9 (23.1 to 49.8)
28 days after Boost Immunization (Day 50)	32.0 (16.9 to 60.5)	42.7 (29.8 to 61.3)	25.4 (15.1 to 42.6)	26.5 (18.4 to 38.2)
63 days after Boost Immunization (Day 85)	29.3 (16.2 to 53.2)	32.0 (19.5 to 52.6)	4.4 (2.4 to 7.8)	5.5 (3.5 to 8.6)
162 days after Boost Immunization (Day 184)	11.0 (6.3 to 19.1)	7.8 (4.1 to 14.6)	5.3 (2.8 to 10.1)	3.1 (2.4 to 4.1)

End point values	BNT162b2 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Titer				
geometric mean (confidence interval 95%)				
7 days after Prime Immunization (Day 8)	1.2 (0.8 to 1.7)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)
21 days after Prime Immunization (Day 22)	7.1 (4.3 to 11.9)	1.0 (1.0 to 1.0)	1.1 (0.9 to 1.2)	1.1 (0.9 to 1.2)
7 days after Boost Immunization (Day 29)	98.7 (62.2 to 156.5)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.1 (0.9 to 1.2)
21 days after Boost Immunization (Day 43)	65.9 (45.5 to 95.3)	1.0 (1.0 to 1.1)	1.1 (1.0 to 1.3)	1.1 (1.0 to 1.3)
28 days after Boost Immunization (Day 50)	57.0 (38.6 to 84.3)	1.0 (1.0 to 1.0)	1.2 (1.0 to 1.4)	1.0 (1.0 to 1.0)
63 days after Boost Immunization (Day 85)	11.6 (7.3 to 18.7)	1.1 (1.0 to 1.3)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)
162 days after Boost Immunization (Day 184)	11.7 (6.1 to 22.3)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.2 (0.8 to 1.6)

End point values	BNT162c2 - Part A Participants Aged 18 to 55 Years - 3 µg			

Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Titer				
geometric mean (confidence interval 95%)				
7 days after Prime Immunization (Day 8)	1.0 (1.0 to 1.0)			
21 days after Prime Immunization (Day 22)	1.4 (1.0 to 2.0)			
7 days after Boost Immunization (Day 29)	1.6 (1.0 to 2.7)			
21 days after Boost Immunization (Day 43)	1.2 (0.9 to 1.6)			
28 days after Boost Immunization (Day 50)	1.1 (0.9 to 1.2)			
63 days after Boost Immunization (Day 85)	1.0 (0.9 to 1.2)			
162 days after Boost Immunization (Day 184)	2.1 (0.7 to 6.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Seroconversion Defined as a Minimum of 4-fold Increase of Functional Antibody Titers as Compared to Baseline for BNT162a1, BNT162b1, BNT162b2 (Younger and Older Dose Ranging Cohorts), and BNT162c2 (P/B)

End point title	Number of Participants With Seroconversion Defined as a Minimum of 4-fold Increase of Functional Antibody Titers as Compared to Baseline for BNT162a1, BNT162b1, BNT162b2 (Younger and Older Dose Ranging Cohorts), and BNT162c2 (P/B)[8]

End point description:

At 7 and 21 days after Dose 1 (Prime Immunization) and at 7, 21, 28, 63, and 162 days after Dose 2 (Boost Immunization). Immunogenicity set - all participants who received at least one dose of IMP and had at least one postbaseline functional antibody titer immunogenicity assessment. 9999 indicates data not available as Day 29 and/or Day 50 were scheduled before approval of protocol version 7 which implemented these visits. 999 indicates confidence interval not calculated as values of at least 3 participants were not available.

End point type	Secondary

End point timeframe:

Up to 183 days following Dose 1

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only reports data for the BNT162a1, BNT162b1, BNT162b2 Dose Ranging, and BNT162c2 Prime/Boost Cohorts.

End point values	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 1 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	6	12
Units: Participants				

7 days after Prime Immunization (Day 8)	0	0	0	0
21 days after Prime Immunization (Day 22)	0	0	0	2
7 days after Boost Immunization (Day 29)	9999	9999	9999	9999
21 days after Boost Immunization (Day 43)	0	2	0	10
28 days after Boost Immunization (Day 50)	0	9999	9999	9999
63 days after Boost Immunization (Day 85)	0	2	0	9
162 days after Boost Immunization (Day 184)	0	1	0	3

End point values	BNT162b1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 10 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 30 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
7 days after Prime Immunization (Day 8)	0	0	0	0
21 days after Prime Immunization (Day 22)	1	3	3	7
7 days after Boost Immunization (Day 29)	11	9999	11	9999
21 days after Boost Immunization (Day 43)	11	9	10	12
28 days after Boost Immunization (Day 50)	11	9999	11	9999
63 days after Boost Immunization (Day 85)	8	9	10	11
162 days after Boost Immunization (Day 184)	6	4	7	8

End point values	BNT162b1 - Part A Participants Aged 18 to 55 Years - 50 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 60 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 20 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
7 days after Prime Immunization (Day 8)	0	0	0	0
21 days after Prime Immunization (Day 22)	7	6	5	6
7 days after Boost Immunization (Day 29)	9999	9999	12	12
21 days after Boost Immunization (Day 43)	11	3	12	11

28 days after Boost Immunization (Day 50)	9999	9999	12	11
63 days after Boost Immunization (Day 85)	11	1	10	8
162 days after Boost Immunization (Day 184)	10	0	5	7

End point values	BNT162b1 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 10 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
7 days after Prime Immunization (Day 8)	0	0	0	0
21 days after Prime Immunization (Day 22)	3	0	0	7
7 days after Boost Immunization (Day 29)	11	7	12	1
21 days after Boost Immunization (Day 43)	12	9	12	11
28 days after Boost Immunization (Day 50)	12	9	11	12
63 days after Boost Immunization (Day 85)	10	8	9	11
162 days after Boost Immunization (Day 184)	10	3	2	6

End point values	BNT162b2 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 30 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 20 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
7 days after Prime Immunization (Day 8)	0	0	0	0
21 days after Prime Immunization (Day 22)	5	6	2	2
7 days after Boost Immunization (Day 29)	12	12	12	12
21 days after Boost Immunization (Day 43)	12	11	12	12
28 days after Boost Immunization (Day 50)	12	12	12	11
63 days after Boost Immunization (Day 85)	12	12	8	7
162 days after Boost Immunization (Day 184)	10	11	7	4

End point values	BNT162b2 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
7 days after Prime Immunization (Day 8)	1	0	0	0
21 days after Prime Immunization (Day 22)	10	0	0	0
7 days after Boost Immunization (Day 29)	12	0	0	0
21 days after Boost Immunization (Day 43)	12	0	0	0
28 days after Boost Immunization (Day 50)	12	0	0	0
63 days after Boost Immunization (Day 85)	12	0	0	0
162 days after Boost Immunization (Day 184)	10	0	0	1

End point values	BNT162c2 - Part A Participants Aged 18 to 55 Years - 3 µg			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Participants				
7 days after Prime Immunization (Day 8)	0			
21 days after Prime Immunization (Day 22)	1			
7 days after Boost Immunization (Day 29)	2			
21 days after Boost Immunization (Day 43)	0			
28 days after Boost Immunization (Day 50)	0			
63 days after Boost Immunization (Day 85)	0			
162 days after Boost Immunization (Day 184)	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Functional Antibody Responses (Titers) for BNT162c2 (SD)

End point title	Functional Antibody Responses (Titers) for BNT162c2 (SD)[9]

End point description:

At Day 1 (Baseline) and at 7, 21, 28, 42, 84, and 183 days after Dose 1 (Prime Immunization). Immunogenicity set - all participants who received at least one dose of IMP and had at least one postbaseline functional antibody titer immunogenicity assessment. 9999 indicates data not available as Day 29 of cohort 0.1 µg was scheduled before approval of protocol version 7 which implemented this visit.

End point type	Secondary

End point timeframe:

Up to 183 days following Dose 1

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint only reports data for the BNT162c2 single dose cohorts.

End point values	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.6 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg SD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Titer				
geometric mean (confidence interval 95%)				
Pre-Prime Immunization (Day 1)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)
7 days after Prime Immunization (Day 8)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)
21 days after Prime Immunization (Day 22)	5.1 (4.8 to 5.5)	5.1 (4.8 to 5.5)	5.3 (4.7 to 6.0)	5.5 (4.8 to 6.3)
28 days after Prime Immunization (Day 29)	9999 (9999 to 9999)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.2 (4.8 to 5.6)
42 days after Prime Immunization (Day 43)	5.1 (4.8 to 5.5)	5.1 (4.8 to 5.5)	5.5 (4.5 to 6.6)	5.1 (4.8 to 5.5)
84 days after Prime Immunization (Day 85)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	6.0 (4.0 to 9.2)	5.0 (5.0 to 5.0)
183 days after Prime Immunization (Day 184)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.5 (4.5 to 6.8)	6.4 (3.7 to 11.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Fold Increase in Functional Antibody Titers as Compared to Baseline for BNT162c2 (SD)

End point title	Fold Increase in Functional Antibody Titers as Compared to Baseline for BNT162c2 (SD)[10]

End point description:

At 7, 21, 28, 42, 84, and 183 days after Dose 1 (Prime Immunization). Immunogenicity set - all participants who received at least one dose of IMP and had at least one postbaseline functional antibody titer immunogenicity assessment. 9999 indicates data not available as Day 29 of cohort 0.1 µg was scheduled before approval of protocol version 7 which implemented this visit.

End point type	Secondary

End point timeframe:

Up to 183 days following Dose 1

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only reports data for the BNT162c2 single dose cohorts.

End point values	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.6 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg SD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Titer				
geometric mean (confidence interval 95%)				
7 days after Prime Immunization (Day 8)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)
21 days after Prime Immunization (Day 22)	1.0 (1.0 to 1.1)	1.0 (1.0 to 1.1)	1.1 (0.9 to 1.2)	1.1 (1.0 to 1.3)
28 days after Prime Immunization (Day 29)	9999 (9999 to 9999)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.1)
42 days after Prime Immunization (Day 43)	1.0 (1.0 to 1.1)	1.0 (1.0 to 1.1)	1.1 (0.9 to 1.3)	1.0 (1.0 to 1.1)
84 days after Prime Immunization (Day 85)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.2 (0.8 to 1.8)	1.0 (1.0 to 1.0)
183 days after Prime Immunization (Day 184)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.1 (0.9 to 1.4)	1.3 (0.7 to 2.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Seroconversion Defined as a Minimum of 4-fold Increase of Functional Antibody Titers as Compared to Baseline for BNT162c2 (SD)

End point title	Number of Participants With Seroconversion Defined as a Minimum of 4-fold Increase of Functional Antibody Titers as Compared to Baseline for BNT162c2 (SD)[11]

End point description:

At 7, 21, 28, 42, 84, and 183 days after Dose 1 (Prime Immunization). Immunogenicity set - all participants who received at least one dose of IMP and had at least one post-baseline functional antibody titer immunogenicity assessment. 9999 indicates data not available as Day 29 of cohort 0.1 µg was scheduled before approval of protocol version 7 which implemented this visit.

End point type	Secondary

End point timeframe:

Up to 183 days following Dose 1

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only reports data for the BNT162c2 single dose cohorts.

End point values	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.6 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg SD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	12	12	12
Units: Participants				
7 days after Prime Immunization (Day 8)	0	0	0	0
21 days after Prime Immunization (Day 22)	0	0	0	0
28 days after Prime Immunization (Day 29)	9999	0	0	0
42 days after Prime Immunization (Day 43)	0	0	0	0
84 days after Prime Immunization (Day 85)	0	0	1	0
183 days after Prime Immunization (Day 184)	0	0	0	1

Statistical analyses

No statistical analyses for this end point

Secondary: Functional Antibody Responses (Titers) for BNT162b2 (Expansion Cohorts 11, 12, 13 and 14; P/B)

End point title	Functional Antibody Responses (Titers) for BNT162b2 (Expansion Cohorts 11, 12, 13 and 14; P/B)[12]

End point description:

At Day 1 (Baseline) and at 7, 14, and 21 days after Dose 1 (Prime Immunization) and at 7, 14, 21, 28, 63, 162, and 343 days after Dose 2 (Boost Immunization). Immunogenicity set - all participants who received at least one dose of IMP and had at least one post-baseline functional antibody titer immunogenicity assessment. 9999 indicates data not available as, according to the protocol, Day 15 assessment was only performed for Cohort 14, and Day 36, Day 43, Day 85, and Day 365 assessments were only performed for Cohorts 11, 12, and 13. 999 indicates confidence interval not calculated as values of at least 3 participants were not available. 99999 indicates data not available as all participants crossed-over to study BNT162-14 before reaching Day 365 or were discontinued due to the reception of a non-trial vaccination.

End point type	Secondary

End point timeframe:

Up to 1 year following Dose 1

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only reports data for the BNT162b2 Expansion Cohorts.

End point values	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg HIV	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg PT	BNT162b2 - Part A Participants Aged 18 to 85 Years - 3 & 30 µg	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C12
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	30	90

Units: Titer				
geometric mean (confidence interval 95%)				
Pre-Prime Immunization (Day 1)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.1 (4.9 to 5.3)
7 days after Prime Immunization (Day 8)	5.0 (5.0 to 5.0)	5.0 (5.0 to 5.0)	5.4 (4.8 to 6.0)	5.3 (4.7 to 6.1)
14 days after Prime Immunization (Day 15)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)
21 days after Prime Immunization (Day 22)	17.4 (9.8 to 30.9)	5.2 (4.7 to 5.8)	5.7 (4.8 to 6.8)	21.9 (17.5 to 27.3)
7 days after Boost Immunization (Day 29)	167.6 (112.0 to 250.7)	12.0 (5.5 to 26.4)	30.7 (21.3 to 44.1)	348.6 (270.8 to 448.8)
14 days after Boost Immunization (Day 36)	206.3 (116.8 to 364.3)	11.5 (5.3 to 24.8)	149.3 (104.0 to 214.4)	379.1 (306.0 to 469.6)
21 days after Boost Immunization (Day 43)	167.6 (93.8 to 299.2)	9.8 (4.8 to 19.7)	119.9 (81.5 to 176.4)	307.8 (250.0 to 378.9)
28 days after Boost Immunization (Day 50)	136.1 (76.2 to 243.0)	11.0 (5.1 to 23.7)	87.7 (62.3 to 123.7)	266.5 (215.9 to 328.8)
63 days after Boost Immunization (Day 85)	50.4 (30.7 to 82.7)	8.3 (5.0 to 13.7)	79.1 (56.7 to 110.2)	99.9 (81.3 to 122.7)
162 days after Boost Immunization (Day 184)	27.0 (16.3 to 44.6)	11.9 (4.0 to 35.3)	19.2 (11.9 to 30.9)	29.5 (23.5 to 37.1)
343 days after Boost Immunization (Day 365)	99999 (99999 to 99999)	99999 (99999 to 99999)	7.1 (-999 to 999)	30.2 (11.7 to 78.2)

End point values	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C14			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Titer				
geometric mean (confidence interval 95%)				
Pre-Prime Immunization (Day 1)	5.0 (5.0 to 5.0)			
7 days after Prime Immunization (Day 8)	6.6 (4.2 to 10.4)			
14 days after Prime Immunization (Day 15)	9.5 (4.8 to 18.7)			
21 days after Prime Immunization (Day 22)	17.9 (9.5 to 33.7)			
7 days after Boost Immunization (Day 29)	286.8 (183.1 to 449.4)			
14 days after Boost Immunization (Day 36)	9999 (9999 to 9999)			
21 days after Boost Immunization (Day 43)	9999 (9999 to 9999)			
28 days after Boost Immunization (Day 50)	103.3 (70.8 to 150.6)			
63 days after Boost Immunization (Day 85)	9999 (9999 to 9999)			
162 days after Boost Immunization (Day 184)	49.8 (33.3 to 74.4)			
343 days after Boost Immunization (Day 365)	9999 (9999 to 9999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Fold Increase in Functional Antibody Titers as Compared to Baseline for BNT162b2 (Expansion Cohorts 11, 12, 13 and 14; P/B)

End point title	Fold Increase in Functional Antibody Titers as Compared to Baseline for BNT162b2 (Expansion Cohorts 11, 12, 13 and 14; P/B)[13]

End point description:

At 7, 14, and 21 days after Dose 1 (Prime Immunization) and at 7, 14, 21, 28, 63, 162, and 343 days after Dose 2 (Boost Immunization). Immunogenicity set - all participants who received at least one dose of IMP and had at least one post-baseline functional antibody titer immunogenicity assessment. 9999 indicates data not available as, according to the protocol, Day 15 assessment was only performed for Cohort 14, and Day 36, Day 43, Day 85, and Day 365 assessments were only performed for Cohorts 11, 12, and 13. 999 indicates confidence interval not calculated as values of at least 3 participants were not available. 99999 indicates data not available as all participants crossed-over to study BNT162-14 before reaching Day 365 or were discontinued due to the reception of a non-trial vaccination.

End point type	Secondary

End point timeframe:

Up to 1 year following Dose 1

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only reports data for the BNT162b2 Expansion Cohorts.

End point values	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg HIV	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg PT	BNT162b2 - Part A Participants Aged 18 to 85 Years - 3 & 30 µg	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C12
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	30	90
Units: Titer				
geometric mean (confidence interval 95%)				
7 days after Prime Immunization (Day 8)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	1.1 (1.0 to 1.2)	1.0 (1.0 to 1.1)
14 days after Prime Immunization (Day 15)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)	9999 (9999 to 9999)
21 days after Prime Immunization (Day 22)	3.5 (2.0 to 6.2)	1.0 (0.9 to 1.2)	1.1 (1.0 to 1.4)	4.3 (3.5 to 5.3)
7 days after Boost Immunization (Day 29)	33.5 (22.4 to 50.1)	2.4 (1.1 to 5.3)	6.1 (4.3 to 8.8)	68.4 (53.3 to 87.7)
14 days after Boost Immunization (Day 36)	41.3 (23.4 to 72.9)	2.3 (1.1 to 5.0)	29.9 (20.8 to 42.9)	74.3 (60.2 to 91.8)
21 days after Boost Immunization (Day 43)	33.5 (18.8 to 59.8)	2.0 (1.0 to 3.9)	24.0 (16.3 to 35.3)	60.4 (49.2 to 74.1)
28 days after Boost Immunization (Day 50)	27.2 (15.2 to 48.6)	2.2 (1.0 to 4.7)	17.5 (12.5 to 24.7)	52.3 (42.7 to 64.0)

63 days after Boost Immunization (Day 85)	10.1 (6.1 to 16.5)	1.7 (1.0 to 2.7)	15.8 (11.3 to 22.0)	19.6 (16.0 to 23.9)
162 days after Boost Immunization (Day 184)	5.4 (3.3 to 8.9)	2.4 (0.8 to 7.1)	3.8 (2.4 to 6.2)	5.8 (4.6 to 7.2)
343 days after Boost Immunization (Day 365)	99999 (99999 to 99999)	99999 (99999 to 99999)	1.4 (-999 to 999)	5.4 (2.1 to 13.8)

End point values	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C14			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Titer				
geometric mean (confidence interval 95%)				
7 days after Prime Immunization (Day 8)	1.3 (0.8 to 2.1)			
14 days after Prime Immunization (Day 15)	1.9 (1.0 to 3.7)			
21 days after Prime Immunization (Day 22)	3.6 (1.9 to 6.7)			
7 days after Boost Immunization (Day 29)	57.4 (36.6 to 89.9)			
14 days after Boost Immunization (Day 36)	9999 (9999 to 9999)			
21 days after Boost Immunization (Day 43)	9999 (9999 to 9999)			
28 days after Boost Immunization (Day 50)	20.7 (14.2 to 30.1)			
63 days after Boost Immunization (Day 85)	9999 (9999 to 9999)			
162 days after Boost Immunization (Day 184)	10.0 (6.7 to 14.9)			
343 days after Boost Immunization (Day 365)	99999 (99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Seroconversion Defined as a Minimum of 4-fold Increase of Functional Antibody Titers as Compared to Baseline for BNT162b2 (Expansion Cohorts 11, 12, 13 and 14; P/B)

End point title	Number of Participants With Seroconversion Defined as a Minimum of 4-fold Increase of Functional Antibody Titers as Compared to Baseline for BNT162b2 (Expansion Cohorts 11, 12, 13 and 14; P/B)[14]

End point description:

At 7, 14, and 21 days after Dose 1 (Prime Immunization) and at 7, 14, 21, 28, 63, 162, and 343 days after Dose 2 (Boost Immunization). Immunogenicity set - all participants who received at least one dose of IMP and had at least one post-baseline functional antibody titer immunogenicity assessment. 9999 indicates data not available as, according to the protocol, Day 15 assessment was only performed for

Cohort 14, and Day 36, Day 43, Day 85, and Day 365 assessments were only performed for Cohorts 11, 12, and 13. 999 indicates confidence interval not calculated as values of at least 3 participants were not available. 99999 indicates data not available as all participants crossed-over to study BNT162-14 before reaching Day 365 or were discontinued due to the reception of a non-trial vaccination.

End point type	Secondary

End point timeframe:

Up to 1 year following Dose 1

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint only reports data for the BNT162b2 Expansion Cohorts.

End point values	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg HIV	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg PT	BNT162b2 - Part A Participants Aged 18 to 85 Years - 3 & 30 µg	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C12
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	30	90
Units: Participants				
7 days after Prime Immunization (Day 8)	0	0	1	1
14 days after Prime Immunization (Day 15)	9999	9999	9999	9999
21 days after Prime Immunization (Day 22)	7	0	1	54
7 days after Boost Immunization (Day 29)	15	4	22	88
14 days after Boost Immunization (Day 36)	15	4	30	88
21 days after Boost Immunization (Day 43)	15	3	29	89
28 days after Boost Immunization (Day 50)	15	4	30	89
63 days after Boost Immunization (Day 85)	13	2	28	84
162 days after Boost Immunization (Day 184)	12	3	12	61
343 days after Boost Immunization (Day 365)	99999	99999	0	10

End point values	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C14			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Participants				
7 days after Prime Immunization (Day 8)	2			
14 days after Prime Immunization (Day 15)	4			
21 days after Prime Immunization (Day 22)	9			

7 days after Boost Immunization (Day 29)	19			
14 days after Boost Immunization (Day 36)	9999			
21 days after Boost Immunization (Day 43)	9999			
28 days after Boost Immunization (Day 50)	19			
63 days after Boost Immunization (Day 85)	9999			
162 days after Boost Immunization (Day 184)	18			
343 days after Boost Immunization (Day 365)	99999			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Local reactions/systemic events: within 7 days after each IMP dose; SAEs: from Day 1 (Dose 1 [Prime]) up to Day 387 (approximately 12 months after Dose 2 [Boost]); other AEs: see below in section 'AE reporting additional description'.

Adverse event reporting additional description:

Timeframe for AE reporting continued:
Other AEs in participants with Dose 2: All AEs from Day 1 up to Day 50 and in addition if assessed as IMP-related from Day 50 up to Day 387; Other AEs in participants without Dose 2: All AEs from Day 1 up to Day 29 and in addition if assessed as IMP-related from Day 29 up to Day 387.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.1 µg

Reporting group description:

BNT162a1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen).

Reporting group title	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.3 µg

Reporting group description:

BNT162a1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162a1 - Part A Participants Aged 18 to 55 Years - 3 µg

Reporting group description:

BNT162a1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the Safety Review Committee [SRC]).

Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 1 µg

Reporting group description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 3 µg

Reporting group description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 20 µg

Reporting group description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 10 µg

Reporting group description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 30 µg

Reporting group description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 50 µg

Reporting group description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b1 - Part A Participants Aged 18 to 55 Years - 60 µg

Reporting group description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the SRC).

Reporting group title	BNT162b1 - Part A Participants Aged 56 to 85 Years - 10 µg

Reporting group description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b1 - Part A Participants Aged 56 to 85 Years - 20 µg

Reporting group description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b1 - Part A Participants Aged 56 to 85 Years - 30 µg

Reporting group description:

BNT162b1: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 1 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 3 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 10 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 20 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 55 Years - 30 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 56 to 85 Years - 10 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 56 to 85 Years - 20 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A Participants Aged 56 to 85 Years - 30 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg HIV

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen), expansion cohort (Cohort 13). ICP = Immunocompromised participants.

Reporting group title	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg PT

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen), expansion cohort (Cohort 13). ICP = Immunocompromised participants, PT = post-transplant.

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 85 Years - 3 & 30 µg

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen), alternative posology dose group expansion cohort (Cohort 11).
.

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C12

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen), adaptive immune response dose group expansion cohort (C12 = Cohort 12).

Reporting group title	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C14

Reporting group description:

BNT162b2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen), B-cell immune response dose group expansion cohort (C14 = Cohort 14).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg

Reporting group description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg

Reporting group description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg

Reporting group description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 3 µg

Reporting group description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (P/B regimen).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg SD

Reporting group description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (single dose [SD] regimen).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg SD

Reporting group description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (SD regimen).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.6 µg SD

Reporting group description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (SD regimen).

Reporting group title	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg SD

Reporting group description:

BNT162c2: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (SD regimen).

Serious adverse events	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 3 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oesophageal carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
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			
Ankle fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
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			
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
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			
Pelvic mass			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
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			
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
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			
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
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	BNT162b1 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 20 µg
Total subjects affected by serious			

adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oesophageal carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Ankle fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Pelvic mass			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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	BNT162b1 - Part A Participants Aged 18 to 55 Years - 10 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 30 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 50 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oesophageal carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Ankle fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Pelvic mass			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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	BNT162b1 - Part A Participants Aged 18 to 55 Years - 60 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 20 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	2 / 12 (16.67%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oesophageal carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Ankle fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pelvic mass			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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	BNT162b1 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 3 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oesophageal carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Ankle fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Pelvic mass			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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	BNT162b2 - Part A Participants Aged 18 to 55 Years - 10 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 30 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oesophageal carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Ankle fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Pelvic mass			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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	BNT162b2 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 20 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 30 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 12 (8.33%)	3 / 12 (25.00%)	0 / 12 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oesophageal carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (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			
Ankle fracture			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Pelvic mass			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (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
Inguinal hernia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (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
Umbilical hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg HIV	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg PT	BNT162b2 - Part A Participants Aged 18 to 85 Years - 3 & 30 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	3 / 15 (20.00%)	0 / 30 (0.00%)

number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oesophageal carcinoma			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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			
Ankle fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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			
Syncope			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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			
Pelvic mass			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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			
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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			
Cystitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 15 (0.00%)	3 / 15 (20.00%)	0 / 30 (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
COVID-19			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
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	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C12	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C14	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 90 (3.33%)	1 / 20 (5.00%)	0 / 12 (0.00%)

number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oesophageal carcinoma			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
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			
Ankle fracture			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
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	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (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
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (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
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
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			
Pelvic mass			

subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
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			
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 90 (0.00%)	1 / 20 (5.00%)	0 / 12 (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
Infections and infestations			
Cystitis			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (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
Urinary tract infection			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
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	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 3 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oesophageal carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Ankle fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Pelvic mass			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.6 µg SD
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)

number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oesophageal carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Ankle fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Pelvic mass			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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			
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
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	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg SD		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 12 (8.33%)		

number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Oesophageal carcinoma			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femur fracture			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pelvic mass			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Umbilical hernia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.1 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162a1 - Part A Participants Aged 18 to 55 Years - 3 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 12 (75.00%)	9 / 12 (75.00%)	5 / 6 (83.33%)
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Systolic hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diastolic hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Surgical and medical procedures			
Dental care			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mole excision			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Papilloma excision			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	1	1	0

Fatigue			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	1 / 6 (16.67%)
occurrences (all)	1	3	1
Feeling hot			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	3 / 12 (25.00%)	8 / 12 (66.67%)	1 / 6 (16.67%)
occurrences (all)	5	14	1
Injection site reaction			
subjects affected / exposed	9 / 12 (75.00%)	8 / 12 (66.67%)	1 / 6 (16.67%)
occurrences (all)	10	15	1
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Vessel puncture site paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Injection site discolouration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injection site hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injection site hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Injection site induration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Medical device site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Physical disability			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Amenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Breast discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Rhinitis allergic			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Lymphocyte count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle strength abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood pressure systolic increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Sunburn			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Thermal burn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cartilage injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint injury			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Extrasystoles			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			

subjects affected / exposed	2 / 12 (16.67%)	1 / 12 (8.33%)	1 / 6 (16.67%)
occurrences (all)	2	1	2
Cervicobrachial syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Head discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Orthostatic intolerance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sudden hearing loss			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinnitus			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Periorbital discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal hypermotility			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bone hypertrophy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Tenosynovitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Genital herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cestode infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BNT162b1 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 3 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 20 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 12 (75.00%)	2 / 12 (16.67%)	6 / 12 (50.00%)
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Systolic hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Diastolic hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Dental care			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mole excision			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Papilloma excision			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	7 / 12 (58.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	7	0	0
Feeling hot			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	4 / 12 (33.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	7	0	0
Injection site reaction			
subjects affected / exposed	4 / 12 (33.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	7	0	0
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discolouration			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Injection site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Injection site pain			
subjects affected / exposed	3 / 12 (25.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	4	0	0
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site haematoma			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Medical device site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Physical disability			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amenorrhoea			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hallucination			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Sleep disorder			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Muscle strength abnormal			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Amylase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood pressure systolic increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Sunburn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Face injury			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cartilage injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Tachycardia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	5 / 12 (41.67%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	10	0	3
Cervicobrachial syndrome			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Head discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Presyncope			

subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Taste disorder			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Tension headache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Orthostatic intolerance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sudden hearing loss			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Asthenopia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Photophobia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Blepharitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital discomfort			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Dry mouth			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Gingival pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin irritation			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone hypertrophy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cestode infection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Polydipsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BNT162b1 - Part A Participants Aged 18 to 55 Years - 10 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 30 µg	BNT162b1 - Part A Participants Aged 18 to 55 Years - 50 µg
Total subjects affected by non-serious			

adverse events			
subjects affected / exposed	12 / 12 (100.00%)	12 / 12 (100.00%)	12 / 12 (100.00%)
Vascular disorders			
Hot flush			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Systolic hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diastolic hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Dental care			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mole excision			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Papilloma excision			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Fatigue			

subjects affected / exposed	6 / 12 (50.00%)	5 / 12 (41.67%)	1 / 12 (8.33%)
occurrences (all)	7	7	1
Feeling hot			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	8 / 12 (66.67%)	10 / 12 (83.33%)	11 / 12 (91.67%)
occurrences (all)	8	16	21
Injection site reaction			
subjects affected / exposed	8 / 12 (66.67%)	11 / 12 (91.67%)	12 / 12 (100.00%)
occurrences (all)	11	19	20
Pyrexia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	1	0	2
Vessel puncture site paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discolouration			
subjects affected / exposed	1 / 12 (8.33%)	2 / 12 (16.67%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
Injection site discomfort			
subjects affected / exposed	5 / 12 (41.67%)	3 / 12 (25.00%)	1 / 12 (8.33%)
occurrences (all)	5	3	1
Injection site erythema			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Injection site haematoma			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Injection site hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Injection site hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site induration			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	4 / 12 (33.33%)	3 / 12 (25.00%)	1 / 12 (8.33%)
occurrences (all)	4	3	1
Malaise			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Medical device site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Social circumstances			
Physical disability			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Amenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Rhinitis allergic			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Body temperature increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Lymphocyte count increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle strength abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood pressure systolic increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Sunburn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cartilage injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	8 / 12 (66.67%)	8 / 12 (66.67%)	5 / 12 (41.67%)
occurrences (all)	15	12	5
Cervicobrachial syndrome			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	2 / 12 (16.67%)
occurrences (all)	1	1	2
Head discomfort			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Taste disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	0	1	2
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Orthostatic intolerance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sudden hearing loss			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear disorder			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			

subjects affected / exposed	2 / 12 (16.67%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	3	1	1
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Pityriasis rosea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	0	1	2
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Muscle tightness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	1
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Pain in extremity			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone hypertrophy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Genital herpes			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

Gingivitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Tinea pedis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Cestode infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Otitis externa			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	3 / 12 (25.00%)
occurrences (all)	0	1	3
Polydipsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BNT162b1 - Part A Participants Aged 18 to 55 Years - 60 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b1 - Part A Participants Aged 56 to 85 Years - 20 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 12 (100.00%)	3 / 12 (25.00%)	4 / 12 (33.33%)
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Systolic hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diastolic hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Surgical and medical procedures			
Dental care			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mole excision			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Papilloma excision			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	10 / 12 (83.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	10	0	0
Injection site reaction			
subjects affected / exposed	6 / 12 (50.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	6	0	0
Pyrexia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Vessel puncture site paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discolouration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			

subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Injection site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site hypoaesthesia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Injection site induration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	3 / 12 (25.00%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	3	0	3
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Medical device site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Physical disability			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast discomfort			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 12 (8.33%)	2 / 12 (16.67%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Insomnia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle strength abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood pressure systolic increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Sunburn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Animal bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cartilage injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 12 (16.67%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	2	1	0
Cervicobrachial syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Head discomfort			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hyperaesthesia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Taste disorder			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Orthostatic intolerance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			

subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sudden hearing loss			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			

subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Back pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone hypertrophy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Cestode infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Polydipsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BNT162b1 - Part A Participants Aged 56 to 85 Years - 30 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 3 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 12 (75.00%)	8 / 12 (66.67%)	7 / 12 (58.33%)
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Systolic hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diastolic hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Dental care			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mole excision			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Papilloma excision			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	1 / 12 (8.33%)
occurrences (all)	0	2	1
Feeling hot			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			

subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	3	0
Injection site reaction			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discolouration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Injection site hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Malaise			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Medical device site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Physical disability			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Amenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	2	0	6

Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle strength abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amylase increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood pressure systolic increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Sunburn			
subjects affected / exposed	0 / 12 (0.00%)	2 / 12 (16.67%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Thermal burn			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Arthropod sting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	3
Face injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Wound			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cartilage injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Cervicobrachial syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Head discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Orthostatic intolerance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dysaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
External ear inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sudden hearing loss			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blepharitis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Conjunctival haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	3 / 12 (25.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	4	0	0
Renal colic			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone hypertrophy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	3	0	1
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cestode infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BNT162b2 - Part A Participants Aged 18 to 55 Years - 10 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 20 µg	BNT162b2 - Part A Participants Aged 18 to 55 Years - 30 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 12 (100.00%)	10 / 12 (83.33%)	11 / 12 (91.67%)
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Systolic hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diastolic hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Dental care			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mole excision			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Papilloma excision			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	4 / 12 (33.33%)	5 / 12 (41.67%)	1 / 12 (8.33%)
occurrences (all)	5	6	1
Feeling hot			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	7 / 12 (58.33%)	2 / 12 (16.67%)	4 / 12 (33.33%)
occurrences (all)	7	2	4
Injection site reaction			
subjects affected / exposed	11 / 12 (91.67%)	9 / 12 (75.00%)	10 / 12 (83.33%)
occurrences (all)	21	9	10
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discolouration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Vessel puncture site erythema			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Vessel puncture site haematoma			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Vessel puncture site pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Vessel puncture site swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Asthenia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Medical device site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Physical disability			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervousness			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle strength abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood pressure systolic increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Sunburn			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Thermal burn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cartilage injury			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Extrasystoles			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 12 (33.33%)	2 / 12 (16.67%)	1 / 12 (8.33%)
occurrences (all)	4	3	1
Cervicobrachial syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Head discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Orthostatic intolerance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			

subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Sudden hearing loss			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	2	0	2
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			

subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Toothache			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Night sweats			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Neck pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone hypertrophy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Tinea pedis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cestode infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BNT162b2 - Part A Participants Aged 56 to 85 Years - 10 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 20 µg	BNT162b2 - Part A Participants Aged 56 to 85 Years - 30 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 12 (33.33%)	7 / 12 (58.33%)	4 / 12 (33.33%)
Vascular disorders			
Hot flush			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Systolic hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diastolic hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Dental care			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mole excision			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Papilloma excision			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Injection site reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pyrexia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discolouration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Injection site hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Medical device site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Physical disability			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle strength abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Blood pressure systolic increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Sunburn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Animal bite			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Cartilage injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Contusion			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 12 (8.33%)	2 / 12 (16.67%)	3 / 12 (25.00%)
occurrences (all)	1	2	4
Cervicobrachial syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Head discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Migraine			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Orthostatic intolerance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Sensory disturbance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sudden hearing loss			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Gingival pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Skin irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Leukocyturia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Muscle tightness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Tendon pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Bone hypertrophy			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Tinea pedis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cestode infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Polydipsia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg HIV	BNT162b2 - Part A ICP Aged 18 to 85 Years - 30 µg PT	BNT162b2 - Part A Participants Aged 18 to 85 Years - 3 & 30 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 15 (20.00%)	11 / 15 (73.33%)	13 / 30 (43.33%)
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Systolic hypertension			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Diastolic hypotension			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Dental care			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Mole excision			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Papilloma excision			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
General disorders and administration			

site conditions			
Chills			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 15 (0.00%)	2 / 15 (13.33%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
Injection site reaction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	2
Pyrexia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Vessel puncture site paraesthesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Injection site discolouration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Injection site hypersensitivity			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Injection site hypoaesthesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Axillary pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site erythema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Vessel puncture site pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site swelling			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Medical device site erythema			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Physical disability			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Amenorrhoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Breast discomfort			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0

Rhinitis allergic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Investigations			

Body temperature increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Muscle strength abnormal			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Blood pressure systolic increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			

subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Platelet count decreased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Weight increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Sunburn			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Cartilage injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Fall			

subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Joint injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Meniscus injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Tooth fracture			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Arthropod bite			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Nasal injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0

Nervous system disorders			
Headache			
subjects affected / exposed	0 / 15 (0.00%)	2 / 15 (13.33%)	3 / 30 (10.00%)
occurrences (all)	0	2	4
Cervicobrachial syndrome			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Head discomfort			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Orthostatic intolerance			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Lymph node pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 15 (0.00%)	2 / 15 (13.33%)	0 / 30 (0.00%)
occurrences (all)	0	3	0
Neutropenia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Sudden hearing loss			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Tinnitus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Ear disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Eye haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Periorbital discomfort			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Dry mouth			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Toothache			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1

Pruritus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Pityriasis rosea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	2 / 30 (6.67%)
occurrences (all)	1	0	2
Muscle tightness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	2 / 15 (13.33%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Neck pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Bone hypertrophy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Pain in jaw			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0

Fungal infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
Rhinitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Tinea pedis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Cestode infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0

Hordeolum			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 15 (0.00%)	2 / 15 (13.33%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
Otitis externa			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Polydipsia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C12	BNT162b2 - Part A Participants Aged 18 to 85 Years - 30 µg C14	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	48 / 90 (53.33%)	9 / 20 (45.00%)	4 / 12 (33.33%)
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	5 / 90 (5.56%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	6	0	0
Hypotension			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Systolic hypertension			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diastolic hypotension			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Dental care			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Mole excision			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Papilloma excision			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	2 / 90 (2.22%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Fatigue			
subjects affected / exposed	2 / 90 (2.22%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Feeling hot			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 90 (2.22%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Vessel puncture site paraesthesia			

subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discolouration			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 90 (0.00%)	3 / 20 (15.00%)	0 / 12 (0.00%)
occurrences (all)	0	3	0
Injection site hypersensitivity			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site hypoaesthesia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	2 / 90 (2.22%)	2 / 20 (10.00%)	0 / 12 (0.00%)
occurrences (all)	4	2	0
Malaise			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site erythema			

subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site pain			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site swelling			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Medical device site erythema			
subjects affected / exposed	0 / 90 (0.00%)	2 / 20 (10.00%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Oedema peripheral			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Physical disability			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			

Dysmenorrhoea			
subjects affected / exposed	2 / 90 (2.22%)	2 / 20 (10.00%)	0 / 12 (0.00%)
occurrences (all)	2	2	0
Amenorrhoea			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast discomfort			
subjects affected / exposed	0 / 90 (0.00%)	1 / 20 (5.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 90 (2.22%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 90 (0.00%)	1 / 20 (5.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hallucination			

subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 90 (0.00%)	1 / 20 (5.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Nervousness			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count increased			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle strength abnormal			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood pressure systolic increased			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lipase increased			

subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 90 (1.11%)	1 / 20 (5.00%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Hepatic enzyme increased			
subjects affected / exposed	2 / 90 (2.22%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Sunburn			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			

subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Face injury			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	2
Wound			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cartilage injury			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	3 / 90 (3.33%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Ligament sprain			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Contusion			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal injury			

subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Supraventricular tachycardia			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	10 / 90 (11.11%)	2 / 20 (10.00%)	1 / 12 (8.33%)
occurrences (all)	10	4	1
Cervicobrachial syndrome			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	2 / 90 (2.22%)	1 / 20 (5.00%)	0 / 12 (0.00%)
occurrences (all)	6	1	0
Head discomfort			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			

subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Orthostatic intolerance			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Anaemia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Lymphopenia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Neutropenia			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sudden hearing loss			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Ear disorder			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			

subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital discomfort			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Dry mouth			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gastrointestinal disorder			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Gingival pain			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal hypermotility			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gingival swelling			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Haematochezia			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Tongue ulceration			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gingival bleeding			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Seborrhoeic dermatitis			

subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	3 / 90 (3.33%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Pruritus			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 90 (3.33%)	1 / 20 (5.00%)	0 / 12 (0.00%)
occurrences (all)	4	1	0
Back pain			
subjects affected / exposed	7 / 90 (7.78%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	7	0	0
Muscle tightness			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	4 / 90 (4.44%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	4	0	0
Neck pain			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone hypertrophy			
subjects affected / exposed	0 / 90 (0.00%)	1 / 20 (5.00%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal stiffness			

subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 90 (0.00%)	1 / 20 (5.00%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Tenosynovitis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	2 / 90 (2.22%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Fungal infection			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 90 (1.11%)	1 / 20 (5.00%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Oral herpes			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Tinea pedis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Cestode infection			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	3 / 90 (3.33%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Otitis externa			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 90 (0.00%)	0 / 20 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Polydipsia			
subjects affected / exposed	1 / 90 (1.11%)	0 / 20 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg	BNT162c2 - Part A Participants Aged 18 to 55 Years - 3 µg

Total subjects affected by non-serious adverse events subjects affected / exposed	5 / 12 (41.67%)	4 / 12 (33.33%)	2 / 12 (16.67%)
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Systolic hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diastolic hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Dental care			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mole excision			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Papilloma excision			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Injection site reaction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discolouration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site induration			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Medical device site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			

subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Physical disability			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Nasal congestion			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle strength abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood pressure systolic increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Sunburn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cartilage injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Nasal injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	4	0
Cervicobrachial syndrome			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Head discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Tension headache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Orthostatic intolerance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sudden hearing loss			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear disorder			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

Pityriasis rosea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone hypertrophy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Gingivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Tinea pedis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cestode infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Otitis externa			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Onychomycosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.1 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.3 µg SD	BNT162c2 - Part A Participants Aged 18 to 55 Years - 0.6 µg SD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 12 (83.33%)	9 / 12 (75.00%)	5 / 12 (41.67%)
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Systolic hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diastolic hypotension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Surgical and medical procedures			
Dental care			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mole excision			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Papilloma excision			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 12 (25.00%)	4 / 12 (33.33%)	2 / 12 (16.67%)
occurrences (all)	3	5	2
Feeling hot			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	2 / 12 (16.67%)	2 / 12 (16.67%)	0 / 12 (0.00%)
occurrences (all)	2	2	0
Injection site reaction			
subjects affected / exposed	1 / 12 (8.33%)	2 / 12 (16.67%)	3 / 12 (25.00%)
occurrences (all)	1	2	3
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discolouration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			

subjects affected / exposed	2 / 12 (16.67%)	3 / 12 (25.00%)	0 / 12 (0.00%)
occurrences (all)	2	3	0
Injection site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Injection site induration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	3 / 12 (25.00%)	2 / 12 (16.67%)	0 / 12 (0.00%)
occurrences (all)	4	2	0
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Medical device site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Physical disability			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Amenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast discomfort			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Insomnia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle strength abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood pressure systolic increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Sunburn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cartilage injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Palpitations			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 12 (33.33%)	3 / 12 (25.00%)	1 / 12 (8.33%)
occurrences (all)	4	4	1
Cervicobrachial syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Head discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Taste disorder			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Orthostatic intolerance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sudden hearing loss			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Periorbital discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	3	0	1
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Back pain			

subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Muscle tightness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bone hypertrophy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cestode infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BNT162c2 - Part A Participants Aged 18 to 55 Years - 1 µg SD		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 12 (91.67%)		
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

Haematoma			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Systolic hypertension			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Diastolic hypotension			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Surgical and medical procedures			
Dental care			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Mole excision			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Papilloma excision			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	3 / 12 (25.00%)		
occurrences (all)	3		
Feeling hot			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Influenza like illness			

subjects affected / exposed	2 / 12 (16.67%)			
occurrences (all)	2			
Injection site reaction				
subjects affected / exposed	9 / 12 (75.00%)			
occurrences (all)	9			
Pyrexia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Vessel puncture site paraesthesia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Injection site discolouration				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Injection site discomfort				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Injection site erythema				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Injection site haematoma				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Injection site hypersensitivity				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Injection site hypoaesthesia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Injection site induration				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Injection site pain				
subjects affected / exposed	1 / 12 (8.33%)			
occurrences (all)	1			
Malaise				

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Axillary pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Non-cardiac chest pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Vessel puncture site erythema subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Vessel puncture site haematoma subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Vessel puncture site pain subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Vessel puncture site swelling subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Asthenia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Medical device site erythema subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Oedema peripheral subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Peripheral swelling subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Discomfort subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Immune system disorders			

Seasonal allergy subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Social circumstances Physical disability subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all) Amenorrhoea subjects affected / exposed occurrences (all) Breast discomfort subjects affected / exposed occurrences (all) Vaginal haemorrhage subjects affected / exposed occurrences (all)	 1 / 12 (8.33%) 2 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Rhinitis allergic subjects affected / exposed occurrences (all) Dyspnoea exertional subjects affected / exposed occurrences (all) Nasal congestion subjects affected / exposed occurrences (all) Oropharyngeal pain subjects affected / exposed occurrences (all)	 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0		

Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hallucination			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Sleep disorder			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Nervousness			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
C-reactive protein increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Lymphocyte count increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Muscle strength abnormal			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Amylase increased			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Blood pressure systolic increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hepatic enzyme increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Weight increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Sunburn			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Thermal burn			

subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Animal bite				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Arthropod sting				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Face injury				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Skin abrasion				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Wound				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Cartilage injury				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Fall				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Joint injury				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Ligament sprain				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Meniscus injury				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Tooth fracture				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Arthropod bite				

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Contusion subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Nasal injury subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Palpitations subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Extrasystoles subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Supraventricular tachycardia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	5 / 12 (41.67%) 5		
Cervicobrachial syndrome subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Dizziness subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Head discomfort subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Hyperaesthesia			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Taste disorder			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Tension headache			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Orthostatic intolerance			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Sensory disturbance			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dysaesthesia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
External ear inflammation			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Sudden hearing loss			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Ear disorder			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Photophobia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Blepharitis			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Conjunctival haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Eye haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Periorbital discomfort			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

Flatulence				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Gastrointestinal disorder				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Gingival pain				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Vomiting				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Haemorrhoids thrombosed				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Nausea				
subjects affected / exposed	1 / 12 (8.33%)			
occurrences (all)	1			
Toothache				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Gastrointestinal hypermotility				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Gingival swelling				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Haematochezia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Tongue ulceration				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Gingival bleeding				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			

Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Skin and subcutaneous tissue disorders Seborrhoeic dermatitis subjects affected / exposed occurrences (all) Skin irritation subjects affected / exposed occurrences (all) Erythema subjects affected / exposed occurrences (all) Hyperhidrosis subjects affected / exposed occurrences (all) Night sweats subjects affected / exposed occurrences (all) Pruritus subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all) Pityriasis rosea subjects affected / exposed occurrences (all) Alopecia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0		
Renal and urinary disorders Pollakiuria subjects affected / exposed occurrences (all) Renal colic	0 / 12 (0.00%) 0		

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Leukocyturia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Muscle tightness			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Tendon pain			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Bone hypertrophy			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Musculoskeletal stiffness			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Tenosynovitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Fungal infection			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Genital herpes			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Gingivitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

Rhinitis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0			
Tinea pedis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0			
Cestode infection subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0			
Gastroenteritis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0			
Tonsillitis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0			
Cellulitis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0			
Herpes zoster subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0			
Hordeolum subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0			
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0			
Otitis externa subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0			
Onychomycosis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0			
Metabolism and nutrition disorders Decreased appetite				

subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Polydipsia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 April 2020	This amendment described the replacement of the product code BNT162c1 with BNT162c2 and changes made in response to feedback from the Paul-Ehrlich-Institut (PEI).
13 May 2020	This amendment described a dose adjustment for the vaccine BNT162c2 and the corrections of some inconsistencies and ambiguities.
26 May 2020	This amendment described updates in response to feedback from the PEI and the Independent Ethics Committee (IEC) following protocol amendment 02 (protocol version 4.0, dated 13 May 2020).
09 June 2020	This amendment described adaption of the protocol to: • Allow the assessment of additional intermediate and low dose cohorts for BNT162b modRNA vaccine candidates to support identification of a suitable dose for Phase II/III evaluation. • Allow the assessment of BNT162b1 modRNA vaccine candidate in elderly subjects, given its favorable safety, tolerability, and immunogenicity profile in younger adults to date and recently available non-human primate immunogenicity data for the BNT162b1 and other modRNA vaccine candidates. • Plan the assessment of BNT162b2 modRNA vaccine candidate in elderly subjects. • Allow the assessment of P/B cohorts for the BNT162c2 saRNA vaccine candidate. • Allow revision of safety assessment & dose limiting toxicity criteria. • Add additional for blood draws for explorative biomarker/immunogenicity research purposes.
26 June 2020	This amendment described updates in response to feedback from the PEI following protocol amendment 04 (protocol version 6.0, dated 09 June 2020).
21 July 2020	This amendment described updates in response to feedback from the PEI and the IEC following protocol amendment 04 (protocol version 7.0, dated 26 June 2020). Changes were also implemented to align data collection and reporting in this trial with the data collection and reporting in other trials with BNT162 vaccines candidates (to facilitate data merging).
05 October 2020	This amendment implemented three additional cohorts (Cohorts 11, 12, and 13) comprising up to additional 150 trial participants aged from 18 to 85 years receiving BNT162b2 only. This amendment also: addressed feedback obtained from the PEI and the IEC following protocol amendment 05 (protocol version 8.0, dated 21 July 2020); introduces logistical simplifications; implemented changes to align data collection and reporting in this trial with the data collection and reporting in other trials with BNT162 vaccines candidates (to facilitate data merging).
28 October 2020	As requested by the IEC, this update reversed the reductions of the intervals between the dosing of trial participants implemented in protocol amendment 06 (protocol version 9.0, dated 05 October 2020) for Cohorts 1 to 10 and Cohort 13.
04 December 2020	This update implemented: a change in the sponsor name; deletion of the participant wellbeing calls given the available clinical data for BNT162b2; addition of text to avoid under reporting of mild COVID-19 related events arising in the trial; addition of a blood draw for CD4+ T-cell counting; removal of outdated content; correction of some errors; updates for clarification; updates of outdated data.

01 March 2021	This update implemented one additional independent cohort (Cohort 14) comprising an additional 20 trial participants receiving BNT162b2. Biomarker data from Cohort 14 were intended to provide characterization of B cell and plasma cell immune responses induced by BNT162b2, and to allow assessment of the durability of responses induced by vaccination in addition to continued follow-up of vaccine safety. There was also a change to concomitant medication reporting to allow capture of vaccinations, e.g., SARS-CoV-2 vaccinations.
12 January 2022	This update implemented changes to the follow-up visits of participants in Cohorts 11 to 13 who received non-trial SARS-CoV-2 vaccinations. For these participants, blood samples for immunogenicity and cell-mediated immune testing were not collected, and they were discontinued from this trial.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/33514629

http://www.ncbi.nlm.nih.gov/pubmed/32998157

http://www.ncbi.nlm.nih.gov/pubmed/34044428

http://www.ncbi.nlm.nih.gov/pubmed/33915773

http://www.ncbi.nlm.nih.gov/pubmed/33888900

http://www.ncbi.nlm.nih.gov/pubmed/35040667

http://www.ncbi.nlm.nih.gov/pubmed/35653438

http://www.ncbi.nlm.nih.gov/pubmed/33524990